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Part II - Issue Papers

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16. ABSTRACT

This report presents the analysis of the economic impact of TSCA section 5 rules on the chemical industry. The industry will be impacted when it introduces new chemicals. Of the six distinguishable consequences for the chemical industry, the most important are the nonquantifiable uncertainty consequences. The more unclear EPA's rationale in making section 5 notice decisions, the greater are the uncertainties.

There will likely be a short-run drop in the number of new chemicals introduced into commerce as chemical companies shift their innovation activities into "safe" chemicals. Current data do not allow a quantitative estimate to be made of the rate of chemical introductions, or the extent of the reduction caused by the section 5 notice requirements; and, even if the data were available, it is doubtful that accurate quantitative predictions could be made.

Smaller companies will face greater uncertainties and the direct costs will more often be a factor in company decisions. In the long run, this regulation may cause the chemical industry to be composed of a fewer number of larger competitors better able to absorb the direct costs and regulatory uncertainty associated with the requirements.

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ECONOMIC IMPACT ANALYSIS OF PROPOSED SECTION 5 NOTICE REQUIREMENTS

PART I: ANALYSIS OF THE IMPACTS ON THE CHEMICAL INDUSTRY OF PROPOSED SECTION 5 NOTICE REQUIREMENTS

PART II: ISSUE PAPERS

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PREFACE

The attached document is a contractor's study done with the supervision and review of the Office of Pesticides and Toxic Substances of the U.S. Environmental Protection Agency. The purpose of the study is to analyze the potential economic impact of proposed section 5 notice requirements. These requirements were prepared by the EPA Office of Pesticides and Toxic Substances to implement section 5 of the Toxic Substances Control Act.

This report was submitted in fulfillment of Task Order Number 3 of Contract Number 68-01-5878 by ICF Incorporated. Work was completed as of August 1980.

This report (consisting of a report and two volumes of appendices) is being released and circulated to coincide with publication in the Federal Register of a notice announcing the availability of the report and of a draft regulatory analysis.

The study is not an official EPA publication. All comments received by EPA will be considered in establishing the final analysis to be published along with the final regulations. Prior to final promulgation of the section 5 notice requirements, the accompanying document shall have standing in any court proceeding only to the extent that it represents the views of the contractor who prepared it. The document cannot be cited, referenced, or represented in any respect in any such proceedings as a statement of EPA's view regarding the subject, the industry or the economic impact of the regulation.

EXECUTIVE SUMMARY

ICF Incorporated was issued a task order by the Environmental Protection Agency to analyze the economic impact on the chemical industry of the Toxic Substances Control Act (TSCA) section 5 rules. These rules would require chemical firms to notify EPA about new chemicals before introduction into commerce. This report presents the results of the analysis.

When the rules are promulgated, there will be six distinguishable consequences for the chemical industry's new chemical introduction process. These are:

1. Direct costs associated with completing reporting requirements;
2. Indirect costs associated with the delay in the introduction of new chemicals;
3. Uncertainty regarding direct costs;
4. Uncertainty regarding length of delay;
5. Possible trade secret disclosure; and
6. Possible restrictions on the ability to market the chemical.

The segments of the chemical industry most likely to be affected by the notice requirements are catalysts, surfactants, cyclic intermediates, rubber processing chemicals, plasticizers, synthetic organic chemicals (NEC), adhesives and sealants, industrial inorganic chemicals (NEC), and plastics and resins.

The section 5 notice requirements have a unique impact. Unlike most regulations, these do not require companies to (1) cease production of specific chemicals, (2) install equipment, or (3) incorporate items directly into the product that will raise its cost. Rather, the notice regulation requires that the administrative apparatus within companies producing new chemical entities notify EPA of their intention to introduce them into commmerce. Although there are readily measurable costs associated with notifying EPA, these costs are not the major source of the economic impact. Rather, the uncertainty about EPA's action on a notice (which is a function of the very existence of TSCA not just Section 5) and the other "difficult to quantify" consequences only indirectly related to the notification rule (e.g., the decision to undertake a health and safety study, protection of trade secrets revealed in the notice, potential restrictive action) will be the major source of impact.

The impact of these direct and indirect effects will occur when the companies make capital allocation decisions. The direct cost of complying with proposed reporting requirements is estimated, based on the October 16, 1979 form, to range from $1,000 to $9,000 per new chemical. However, this is the least important cost factor influencing chemical company decision making. When firms make capital allocation decisions -- whether or not to invest in a new product, for example -- the uncertainties associated with possible EPA actions will generally outweigh the direct costs of complying with notice requirements.

The nonquantifiable uncertainty consequences represent a major impediment to new product development if firms are unable to obtain adequate information about EPA's rationale in making notice decisions. Stated differently, the economic impact of section 5 notice requirements is primarily a function of EPA's regulatory practices, not the administrative costs of notification.

Smaller companies may suffer disproportionately from the uncertainty caused by notice requirements because they generally have less access to expertise about government decision making and normally direct fewer resources toward overhead activities which could provide this expertise. In addition, these companies may also face relatively larger direct costs per new product as a result of their reliance on low volume products which may generate lower absolute revenues and require the submission of more notices.

One likely result of these regulations will be a reduction in the number of new chemicals introduced into the market in the short run. In the long run, chemical companies can be expected to shift their innovative activities to "safe" chemicals. What constitutes a "safe" chemical depends on the state of chemical knowledge and EPA administrative practices with regard to various chemicals. The point is that efforts to reduce the uncertainties created by notice requirements are likely to influence the mix, if not the volume, of chemicals available in the marketplace. While it is clear that any initial drop in the introduction of new chemicals cannot help the current economy, it is difficult to estimate the magnitude of any near-term macroeconomic effects. This inability is attributable in part to limitations in techniques of macroeconomic analysis, but more importantly to the uncertainty of EPA's use of notice requirements data and the lack of data on chemical innovation.

On the basis of current data, it is difficult to estimate either the industry's rate of new chemical introductions or the extent of the reduction caused by the section 5 notice requirements. Even with all of the necessary data to measure the current rate and the likely reduction (data that industry has been reticent to provide), it is doubtful that the level of the reduction could be predicted *ex ante*.

Without the ability to quantify any but the direct costs of these regulations or to estimate the change in the rate and composition of new chemical introductions, economic theory must remain the primary source of insight into the effects of notice requirements. Theory would predict that a drop in the rate of introductions will probably occur, that the industry and the economy will probably suffer at minimum the costs involved in the transition from "unsafe" to "safe" chemicals and that, in the long run, the industry may be composed of fewer, larger competitors better able to absorb the direct costs and regulatory uncertainty associated with the section 5 notice requirements.

PART I

ANALYSIS OF IMPACTS ON THE CHEMICAL INDUSTRY OF PROPOSED SECTION 5 NOTICE REQUIREMENTS

CHAPTER 1

BACKGROUND AND PURPOSE

The Environmental Protection Agency (EPA) published proposed premanufacture notification rules in the Federal Register on January 10, 1979 (44 FR 2242), hereafter referred to as the January 10th proposal under section 5 of the Toxic Substances Control Act (TSCA). After reviewing public comments, EPA reproposed a portion of these rules in the Federal Register of October 16, 1979 (44 FR 59764), hereafter referred to as the October 16th proposal.

A preliminary economic impact analysis, prepared by Arthur D. Little, Inc. (ADL) for EPA, was published concurrently with the January 10th proposal. This analysis estimated the costs of preparing section 5 notices and briefly examined their potential impact on new chemical development. In addition, a unit cost analysis for the October 16 proposal form was also completed by ADL.[1]

EPA engaged ICF Incorporated to conduct an economic analysis of several regulatory alternatives (developed by EPA) for implementing section 5 and a study of the impacts of this program on the chemical industry. Specifically, ICF was asked to extend the ADL preliminary analysis to address impacts on industry performance and structure and impacts on the economy.

ICF Incorporated performed six tasks:

1. developed project workplan;
2. collected data;
3. assessed feasibility of formal approaches to economic impact analysis;
4. analyzed regulatory provisions;
5. performed cost analysis of processor reporting and minimum guidance reporting; and

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[1] These documents, Impact of TSCA Proposed Premanufacture Notification Requirements, December 1978, and Estimated Costs of Preparation and Submission of Reproposed Premanufacture Notice Form, October 1979, are available from the EPA Industry Assistance Office.

6. performed economic impact analysis (based on previous tasks).

Tasks 1 through 5 were necessary to provide the framework for the economic analysis under Task 6. To a considerable extent, the output of these tasks determined the appropriate approach to Task 6.

The details of the methodology are presented in the next chapter.

CHAPTER 2

A METHODOLOGY FOR ANALYZING THE ECONOMIC IMPACT OF REGULATIONS IMPLEMENTING SECTION 5 OF TSCA

This chapter presents an ideal methodology for measuring the economic impact of the new chemical notice information provisions in section 5 of the TSCA and is organized around two topics: (1) the proposed analytical method, and (2) assumptions made in creating the methodology. This chapter is similar to the methodology published in the Federal Register on June 10, 1980.

The analytical method section of the chapter is divided into two subsections. The first subsection describes an overall approach to the economic analysis of regulations that was amended to account for the unique aspects of this set of regulations. The second subsection lists the particular questions that were addressed.

The assumptions section discusses one procedural and five substantive assumptions used in developing this methodology.

On the basis of comments received concerning the methodology and data limitations faced during the study, we amended the methodology so that greater emphasis was placed on the qualitative factors than on the quantitative factors presented in this chapter.

ANALYTICAL METHOD

Approach to Economic Impact Analysis

The first task of an economic impact analysis is to create a baseline against which the effects of the notice regulations can be measured. This baseline should constitute an economic picture of the industry independent of the TSCA regulations but dependent on other changes in the regulatory and legal environment (e.g., liability laws, OSHA, CPSC). In order to develop a baseline, substantial data about the companies within the industry and the industry's role in the U.S. economy are needed. Because the chemical industry produces a diverse set of products which will be impacted differently by premanufacture requirements, it is necessary to segment the industry. Considerable data is needed for each segment, and for this analysis it is important to obtain:

- production data over time that distinguishes between intermediate and final products, notes capacity utilization rates and expansion plans and, when possible, denotes new vs. old product relationships;

- sales volumes or uses over time;
- price histories;
- existence and prices of substitutes;
- financial profiles of producers;
- import/export trends;
- engineering processes;
- research and development expenditures;
- decision rules and processes for new chemical introductions; and
- amount, type, and cost of health and safety testing.

This data permits tentative assessments of:

- market concentration;
- degree of vertical and horizontal integration;
- competitiveness and forms of competition;
- capital budgetary decision processes; and
- demand and supply determinants.

Using this picture of the industry, the analysis requires a demand forecast for the industry's products and a concomitant supply forecast.

Demand Forecast. It is rare that new chemicals subject to section 5 notice requirements will be consumed directly by individual consumers. In almost every instance the chemical industry segment produces intermediate products that are substantially altered before reaching the final consumer. Tracing the demand for these products is exceedingly difficult because of this level of detail; moreover, little or no existing econometric forecasts are available. Thus, we are forced to rely on a projection technique unique to the segment or on projections provided by companies within the impacted segments.

We use historical trend lines to project future developments when such trends appear reliable, and in other cases we use industry-provided projections. The choice was necessarily judgmental.

Supply Forecast. Once the overall baseline demand projection is prepared, it may be necessary to differentiate how this demand will affect individual chemical manufacturers. By examining the following areas, potential recipients of the changed demand might be identified:

- whether the markets are geographically isolated;
- relative strength of competitors and their varying abilities to attract capital;
- individual company product mix and how it might change over time; and
- whether foreign competition will have a significant impact on domestic production.

These factors are important because they can lead to an alteration in the structure of the segment. If they significantly affect the structure, they will affect the economics of the industry and should be reflected in the baseline forecast.

Changes as a Result of Section 5. The next step is to identify the economic impacts on the industry that may result from section 5 notice requirements . If the baseline is properly constructed, sufficient information will have been generated to provide not only a benchmark against which to measure the effects of section 5 notice requirements, but also a useful analytic framework for projecting the economic consequences resulting from implementation of the requirements.

Special Questions

Regulatory impacts can be measured at three different levels: at the level of individual companies affected by regulation, at the more aggregate level of an industry affected by regulation, and at the broad level of the U.S. economy. The impacts on individual companies and the impacts on industry are derived primarily from an analysis of (1) innovation, (2) market structure, and (3) profits. Impacts on the U.S. economy are derived from the analysis of industry impacts.

The five most critical subjects that we examined in our analysis were innovation, market structure, profits, GNP and employment, and foreign trade. Each is discussed below. (This should not be construed to mean that we did not address all of the elements of a typical economic analysis, as shown above, only that these are the five most critical.)

Innovation. Innovation is a broad term which is used throughout this report to refer only to the new chemical entity development process. Process innovation and creation of new mixtures are excluded from the definition in this report.

The first step in examining the impact of premanufacture notification on the stream of new chemicals introduced each year was to characterize the historical pattern for each segment. Using this baseline we then tried to estimate the way in which section 5 notice requirements would alter that stream. From a methodical survey of previous studies, trade journals, buyer's guides, and U.S. International Trade Commission data on chemical production, we developed an understanding of the role that innovation plays in each segment. Lacking detailed industry input, we were unable to develop detailed, historical, new product introductions in terms of research and development, sales, physical quantities, and expected and actual returns.

Having characterized the baseline stream of new chemicals on the basis of public information, we attempted to explore the chemical firms' decision-making process regarding new chemical introduction. Some information about this process was available in the comments made by firms about the section 5 notice requirement proposals, and more information was obtained from a survey of trade journals. However, the bulk of data on firm decision-making processes was, of course, in the possession of chemical firms and, in some cases their customers. Lacking direct access to this data, we had to rely on industry experts to provide insight into these processes.

With this information we attempted to answer the following questions for typical chemical companies in different segments of the industry:

1. How much is budgeted for R&D and how is that amount determined?

2. What are the key factors in the decision to produce a new chemical?

3. How important is time in the R&D and the commercialization of new chemicals?

4. How important is confidentiality to the success of a new chemical venture?

Combining the information on the baseline stream of new chemicals, firm decision-making processes, and the estimates of the costs of completing the forms developed earlier, we intended to estimate the impacts of the section 5 notice program on innovation in each segment. As subsequent pages will reveal, segment detail proved more elusive in practice than in theory.

Market Structure. There are four questions about market structure that we addressed. The information came from United States International Trade Commission (USITC) data, buyers' guides, trade journals, other literature sources, and industry experts.

1. Who are the competitors in each segment?

2. What form does their competition take--pricing, product differentiation, new product development, other?

3. What role do small firms play within the segment?

4. Does company size influence the kinds of new chemicals produced?

Profits. Four questions concern the role of profits in segment growth:

1. What profits are associated with new chemicals and how do they compare to profits on established chemicals?

2. To what extent are companies dependent on profits in the development of new chemicals?

3. What do companies do with their profits and other cash flows? What are their sources and uses of funds?

4. With what degree of certainty are new chemical profit streams estimated?

The literature, comments from companies, and industry experts provided the information to answer these questions. In particular, question four has been discussed in many of the public comments on prior proposals.

GNP and Employment. In this part of the analysis (and the foreign trade area as well) we intended to aggregate segment projections to determine the overall impact of notice requirements on the U.S. economy. Several economic forecasters (DRI, Chase Econometrics, etc.) of the U.S. economy have previously addressed these questions, and we intended to replicate their basic methodological approach using segment projections. Given the lack of these quantitative segment projections, we instead addressed these related questions:

1. What is the relationship between chemical industry indicators and general economic indicators?

We reviewed existing model data on the GNP increment provided by chemical segments to estimate the degree to which a given percentage change in a chemical segment growth would be reflected in a GNP percentage change. We also reviewed input-output data to determine the effect the chemical industry has on the economic performance of other individual industries.

2. To what extent is innovation in other industries dependent on chemical industry innovation?

We relied for the most part on the literature and on independent experts highly experienced in the chemical industry for this information. The information provided a multiplier to assess the adverse impact on other industry innovation.

3. What has been the relationship between employment and sales in the chemical industry?

To adequately assess this relationship, we have obtained chemical industry sales information from the U.S. Department of Commerce and employment information including productivity from the U.S. Bureau of Labor Statistics (BLS). We have also gathered information on other potential impacts on chemical industry employment from the literature and from chemical industry interviews. As we explain later, the inability to quantify the program's direct uncertainty effects precluded the quantification of the GNP and Employment impacts.

Foreign Trade. Most of the foreign trade questions have been answered through the literature search, discussions with trade associations, and interviews with government officials. A few would have been aided by greater industry input.

1. What types of chemicals are handled in foreign trade?

2. Do U.S. chemical firms have many foreign subsidiaries? What types of relationships exist among them? How do multinationals fit into the particular segments?

3. Does international competition vary across the industry segments? How do foreign chemical firms' R&D programs compare to U.S. firms' programs?

4. To what degree are chemicals developed by U.S. firms licensed to foreign firms for production?

5. What are the factors influencing the locating of R&D, test marketing, and production activities?

ASSUMPTIONS ABOUT THE METHODOLOGY

To perform this particular analysis we made certain procedural and substantive assumptions.

Procedural Assumption

Without question, the most important procedural assumption was that industry could be used as a source of specific data about particular questions raised during our review of publicly available data. This was an important assumption because, although the industry may not be completely objective, it was a potentially excellent source of data. It was our intention to use the industry--through interviews and meetings with trade associations--in a very directed way. We wanted to ask them to supply data in response to specific questions which were developed after our analysis of the publicly-available data. The combination of public and industry sources certainly provided a more substantive and sound analysis. Tthe trade associations we contacted explained that they were not in possession of the extremely confidential detailed data we sought, and generally they encouraged us to interview individual companies.

If, however, we had relied solely on the individual companies to tell us what they would do, we believe we might have gathered potentially unsubstantiable data for two reasons. First, regulations implementing TSCA are not final at this time. Therefore, each potential industry interviewee would have a different picture of the TSCA regulatory program in his mind and would tell how he will react to the program as he perceives it. Second, we think it unlikely that industry interviewees would be able to distinguish section 5 impacts from those of TSCA in general. Given these problems, we chose instead to rely on a selected group of independent industry experts as a major source of data.

Substantive Assumptions

Five substantive assumptions essential to the form of analysis and methodology were:

1. The baseline projection assumed that no TSCA exists and covered the entire chemical industry.
2. To the extent possible, results were quantified. In most cases, the direct impact was provided.
3. The non-baseline projections of chemical industry supply and demand were based on comprehensive program options.
4. The appropriate segmentation scheme was chemical-entity based.
5. Previous estimates of the number of chemicals that will be introduced without TSCA are reasonable and are unlikely to be improved through further analysis.

The Baseline Projection Will Assume No TSCA and Cover the Entire Industry

This assumption has two dimensions: the scope of the chemical industry to be studied and the choice of a baseline regulatory program. Section 5 has no direct impact on currently manufactured chemicals. Therefore, it can be argued that the regulations cannot directly impact these chemicals and that the scope of the economic analysis should only be directed at new chemicals. We would note, however, that in the long run the potential lack of introduction of new chemicals would affect existing chemical markets, the industry, and the U.S. economy. Accordingly we concluded that the appropriate baseline should include both new and existing chemicals consistent with the latter approach.

The second dimension is the decision to assume no TSCA as the baseline. If the baseline were any set of section 5 regulations that could potentially cause significant changes in the industry, it would be practically impossible to develop a defensible data base to project impacts, because no usable historical data would exist. Consequently, we believe the baseline should be the "no-statute" case. Although we will assess the difference among various program formulations, we plan for these to be projections from a baseline that assumes no TSCA. Performing the analysis this way allows us to consider historical data about the industry in developing working hypotheses about demand factors, supply factors, market structure, degree and forms of competition, and concomitant conduct and performance.

To the Extent Possible, Results Will Be Quantified. In Most Cases Range Estimates Will Be Provided.

Although attempts have been made to measure precisely the effects of changes in new chemical introductions, ICF has, in a qualitative analysis, projected that the weight of program changes will fall on the companies, the industry, and the U.S. economy. Chemicals are not economic units; they are, rather, the prime factor in an analysis of this type.

We believe that the results of proposed changes in chemical introductions cannot be assessed qualitatively, because the data we have will not yield defensible, measurable estimates. We have, however, established a baseline with historical quantitative data.

An example of the problems involved in quantifying the impact of section 5 is the difficulty in estimating the effect on employment. Because section 5 is a premanufacture rule, it does not directly cause existing plants to close (though it may indirectly cause plants to close due to a restructuring of the industry), but instead impedes development of potential new plants. For example, if a new chemical simply replaced an old chemical, then it would be possible to associate only slight employment impacts with changed income and profit flows to the industry. Clearly, measurement of this kind of consequence is subject to considerable error, both because it is removed from the activity directly affected and because it is based on other estimates of direct impacts.

The Non-baseline Projection Was Derived from Comprehensive Program Options

Comprehensive program options (CPOs) are combinations of alternatives available to resolve numerous regulatory issues. If two items in a new regulatory program were unresolved and there were 3 options for each, there would be nine possible CPOs. There are two reasons why CPOs should delineate the boundaries of the economic projections. First, the alternative to comprehensive analysis is issue-specific analysis. This kind of analysis requires specificity of data well beyond that currently available.

Second, it is probable that the bulk of the economic impact may be the existence of the program itself without regard to the particular implementation plan (choice among issue alternatives). Thus, we believe that broad options which combine a set of issue alternatives must be examined; but they are only examined to provide indications of the relative impact. For example, the economic impact of any confidentiality provision, no matter how structured, may be substantial. Likewise, even without a form, the requirement to notify may represent the bulk of the impact. In both cases, the incremental difference among the individual issue options may be quite small, but, if combined with several other issues' alternatives, that difference might be considerable.

Our approach, therefore, is to analyze the comprehensive program options which have been developed by EPA. They are based on combinations of program element (issue-specific) options. This approach provides useful information about the relative costs of various CPOs.

To conclude, we favored the CPO approach because (1) the major economic impact was the existence of the program without regard to the issue-specific option chosen, (2) the data do not exist to perform issue-specific analysis with any rigor, and (3) the reasonableness of the regulations depended on the marginal cost-effectiveness of the regulatory program, which should be readily identifiable from the CPO analysis.

The Appropriate Segmentation Scheme was Chemical-Entity Based

In order to estimate the magnitude of the effect of premanufacturing notification on the introduction of new chemicals, it is necessary to characterize past chemical innovation. For a sector as large and diverse as the chemical industry, this analysis is greatly facilitated by disaggregating the industry into smaller units more suitable for study.

Because of the availability of economic data from the U.S. Bureau of the Census, it is tempting to divide the industry along Standard Industrial Classification (SIC) lines. Unfortunately, these categories bear no relation to the need for filing section 5 notices. Instead, SICs fragment individual chemicals according to their source and use--both distinctions to which the requirement to provide notice under section 5 is blind. A single compound like methanol, for example, is classified in two segments depending upon whether it is derived from wood (SIC 2861) or petroleum (2869). Similarly, ammonium hydroxide is listed separately as an industrial inorganic chemical (2819), a household cleanser (2842), and a nitrogenous fertilizer (2873), despite the fact that only one notice would have to be submitted if the chemical were new.

In addition to assigning chemicals to many different categories, SICs also include mixtures such as paints (285). Such combinations are not subject to section 5 regulations and would be affected only indirectly through their components.

SICs are awkward vehicles for studying chemical innovation because they are not chemical groupings. An alternative segmentation scheme, based on common divisions of chemicals and chemical science, is shown in Exhibit 2-3. The portion of the analysis that focuses directly on chemical innovation requires categories based on chemical identities. For other aspects of the analysis we have regrouped the segments.

The Inorganic Chemical group consists primarily of acids, bases, and salts of the more common elements. These compounds are not expected to be the subject of substantial innovation. The majority of these chemicals are produced in large quantities.

High Polymers are chain-like macromolecules comprised of an indefinite number of smaller molecules (monomers) which are chemically bonded. Most synthetic structural materials, such as plastics and rubbers, are made of such polymers and usually produced in large quantities. Although the monomeric units change little over time, new polymers are constantly being developed to adapt to new uses.

EXHIBIT 2-3

SEGMENTATION SCHEME

Segment	Component Products	Roughly Corresponding SIC Codes
Inorganic Chemicals	Alkalies and Chlorine	2812
	Industrial Gases	2813
	Inorganic Pigments	2816
	Inorganic Acids	28193,4
	Potassium and Sodium Compounds	28197
	Fertilizers	2873,4
	Industrial Inorganic Chemicals, NEC	28195,6,9
High Polymers	Thermoplastic Resins	28213
	Thermosetting Resins	28214
	Synthetic Rubber	2822
	Organic Fibers, Non-Cellulosic	2824
Amphipathic Compounds	Soaps and Detergents	2841
	Surfactants	2843
	Fatty Acids	28992
Elementary Organic Chemicals	Primary Petrochemicals	2911
	Gum and Wood Chemicals	2861
	Cyclic Crudes	28655
Organic Chemicals, NEC	Cyclic Intermediates	28651
	Organic Dyes and Pigments	28652,3
	Miscellaneous Cyclic Chemical Products	28691
	Miscellaneous Acyclic Chemical Products	28692
	Rubber-Processing Chemicals	286933
	Plasticizers	286935
	Synthetic Organic Chemicals, NEC	28695
	Organic Explosives	2892
Catalysts	Catalytic Preparations	28198
Other Chemical Products	Cellulosic Fibers	2823
	Polishes and Sanitary Goods	2842
	Paints and Allied Products	2851
	Adhesives and Sealants	2891
	Explosives	2892
	Printing Ink	2893
	Carbon Black	2895
	Salts, Essential Oils, and Chemical Preparations, NEC	28991,5

Fatty Acids are weak organic acids isolated from animal or plant fats or oils. Reaction with inorganic bases yields soaps. Other detergents, such as the linear alkyl sulfonates, are made synthetically from simpler organic chemicals. These substances are amphipathic in that they are soluble in both water and oil. Innovation is expected to be low to moderate.

The Elementary Organic Chemicals are the simple alkanes, olefins, and aromatics which can be obtained directly from petroleum refining. Paraffins and asphalt are also included in the category. Little or no innovation is expected in this group. These substances are the basic building blocks for all organic chemicals and are produced in very large quantities.

Organic Chemicals are used as intermediates for synthesizing chemicals in most of the other categories and also have a variety of uses as end products. Innovation is rapid in this area, and the amounts produced vary.

Catalysts contain both organic and metallic constituents. They are commonly used in small quantities as synthetic reagents and fuels. Because the field is still in its infancy, innovation is expected to be quite high.

Other Chemical Products contains a variety of products which do not fit into the other categories and may have low rates of innovation.

In Exhibit 2-4 we show some of our expected characteristics for each segment. Within each segment economic analysis is performed along product-market lines. For example, within the Other Chemical Products category we developed nine profiles roughly along SIC segments.

EXHIBIT 2-4

GENERAL CHARACTERISTICS EXPECTED FOR EACH SEGMENT

Segment	Innovation	Production[a]	Non-Occupational Exposure
Inorganic Chemicals	L	M-H	V
High Polymers	H	H	H
Amphipathic Compounds	L-M	M-H	M-H
Elementary Organic Chemicals	L	H	V
Organic Chemicals, NEC	H	V	V
Catalysts	H	L	L
Other Chemical Products	V	V	V

Index Key:
L = Low
M = Moderate
H = High
V = Variable

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[a] Production quantities and exposure levels for new chemicals in each group will generally be lower than average.

In concept, our segmentation scheme did not differ greatly from one proposed earlier by ADL. We grouped ADL's 41 segments according to chemical characteristics. Because business enterprises of all sizes produced similar types of chemicals, we split the chemical segment, as best we could, in order to enhance economic discussion. In the case of primary petrochemicals, we combined ADL's four segments into one.

Previous Estimates of the Number of New Chemicals That Will Be Introduced Without TSCA Appear Reasonable and Are Unlikely to be Improved Through Further Analysis

Both Foster D. Snell, Incorporated in 1975, and ADL in 1978, have estimated the number of new chemicals introduced annually. ADL projected the number to be 3,000, of which 2,000 are almost exclusively for R&D purposes. For the remaining 1,000, only 300 are produced in quantities greater than 1,000 pounds. Foster D. Snell estimated 3,300 new substances, a figure close to the ADL estimate.

Three ways to obtain information about the number of new chemicals introduced annually are: (1) to use buyers' guides, (2) to extrapolate from patent data, and (3) to survey the industry. All three approaches have been used in previous analyses, and the ADL estimates considered the results of all three. For this reason, we have used the ADL estimates.

We did attempt, however, to refine the ADL estimate of the likely sales growth over time for new chemicals and the likely cash flow associated with them. Using the cash flow streams extrapolated from the sales data, we created net present values of new chemical investments under differing assumptions about how the uncertainty consequences affected expected real returns. Then, we compared the direct cost consequences of filling out the notice to the total investment. From this comparison, we made a judgement about the likelihood of the chemical not being introduced.

This financial analysis approach initially appeared the most useful way to explore the problem of new chemical introduction. However, the lack of data about past new chemical introduction made these results too speculative to be included in this report. Appendix C in "Appendix: Volume 1" provides the details of the analysis performed.

CHAPTER 3

DATA SOURCES AND COLLECTION

ICF considered the following sources of data in preparing this report: industry interviews, formal contact with trade associations, chemical industry literature, government statistics, trade publications, chemical marketing literature, and previous studies bearing on chemical innovation. Although ICF used all these sources to varying degrees, most information came from: publicly-available data in trade journals, in literature, and in previous studies about the chemical industry and innovation; the previous work performed by ADL, including their industry interviews; a meeting of several independent chemical industry experts (whose views are not necessarily reflected in this analysis, but who were a source of data); those industry representatives willing to provide information; and the public record on the January 10th and October 16th proposals.

PUBLICLY-AVAILABLE DATA

ICF developed initial profiles of the industry segments and identified data gaps to be closed by industry experts and industry representatives by first consulting the trade literature. The documents reviewed included all of the issues as far back as 1965 of Chemical Marketing Reporter, Chemical Week, Chemical and Engineering News, and Chemical Purchasing. ICF also examined Stanford Research Institute's confidential reports on chemical segments and the various volumes of the Kline Guide to the Chemical Industry, the Census of Manufactures, U.S. Industrial Outlook, Current Industrial Reports, and annual reports and 10-Ks of major competitors in selected industry segments.

ARTHUR D. LITTLE STUDIES

The second important source was ADL's previous work. ICF used three components of ADL's work as sources of data for the analysis. The first was the data from their economic analysis of new chemical introductions. Although ICF discovered that the sample was skewed to the low end of the new chemical sales volumes, ICF used the data because it was representative of the mix of new chemical sales of companies in the $10-200 million annual sales range--companies with the potential to be affected more severely, according to the rules, than larger companies.

Secondly, the estimates of the cost of providing specific notice information to EPA was the building block for cost estimates ICF made for the minimum reporting guidance, processor reporting requirements, and importer reporting requirements.

The third aspect of ADL's work that ICF used initially was their methodology for estimating the number of new chemicals that would not have been introduced if section 5 requirements had been in effect at the time of their introduction. Their analytical approach with which ICF concurred was to perform discounted cash flow analysis (DCF) of potential new chemicals based on new chemicals introduced in the past. As developed in Appendix C, some aspects of their analysis were not refined to the extent ICF believes they should have been. ICF performed this refinement to the extent possible and in the Appendix shows how dramatically different the results could be.

INDUSTRY REPRESENTATIVES WILLING TO PROVIDE INFORMATION

ICF met with representatives from the Chemical Manufacturers Association (CMA), the Synthetic Organic Chemicals Manufacturers Association (SOCMA), the Chemical Specialties Manufacturers Association (CSMA), the Soaps and Detergent Association, and the National Paint and Coatings Association to discuss both our approach and our data needs. Additionally we contacted the Society of Plastics Industry, the Man-Made Fibers Association, the Dry Color Manufacturers Association, the Adhesives Council, the Adhesives Manufacturers Association, and the American Importers Association. A critical piece of data that ICF sought was information on research and development costs, sales volumes, and profit margins of new chemicals introduced in the past on an industry segment-specific basis. All industry representatives expressed doubt that ICF could obtain this type of data on new chemicals introduced in the past because of the highly confidential nature of such information. Several industry representatives did share with us specific information about their companies and their segments of the industry. ICF incorporated this data into the analysis. ICF and EPA are still attempting to meet with industry representatives in a continuing effort to obtain additional data regarding the various industry segments.

MEETING OF INDEPENDENT CHEMICAL INDUSTRY AND INNOVATION EXPERTS

After reviewing the ADL interview notes and after learning from the trade associations that they could not finish the needed raw data, we realized that obtaining representative data would require either an extensive and time-consuming interviewing program or a very detailed formal questionnaire. Alternatively, a group of industry and innovation experts could be convened to discuss the chemical industry and its segments. ICF chose to convene a panel of such experts. The experts supplied data and analysis during a two-day discussion of the impact of the notice requirements on the chemical industry.

The backgrounds of the experts were varied. Two participants were academics who have studied innovation. One was the author of numerous articles on innovation in the chemical industry. The three other participants, independent consultants to the chemical industry, represented a total of 100 years of industry experience. Each had his own perspective on industry problems. One came from a marketing background. Another had held a variety of R&D positions and owned patents on some chemicals. The third had been a general manager and senior executive for a major chemical company before becoming an independent consultant and academic. Their resumes are available upon request.

The experts provided valuable information relative to the focus of the analysis and the innovative sector of the industry. First, they cautioned us against taking too myopic a view of the notice requirement. They recognized the need to identify those consequences associated solely with the notice requirement. But they also cited examples of past analyses that had been too narrowly focused and that had, as a result, completely overlooked the broader implications of regulatory programs. In addition, the experts provided more specific data on the innovative sectors of the industry, that is, those segments of the industry that had routinely introduced new chemical entities or that gave signs of doing so. For example, they furnished us with estimates of the expected gross margins on new products and the number of competitors broken down by company size -- in annual sales volume. They considered this last factor crucial to understanding of the impact of the notice requirement.

PUBLIC COMMENT ON EARLIER NOTICE PROPOSALS

The final important source of data was the public record on the January 10th proposal and October 16th proposal concerning the notice requirement. This source was particularly helpful in performing the issues analysis presented in Chapter 5.

CHAPTER 4

IMPACT OF SECTION 5 NOTICE REGULATION

This chapter presents an overview of the costs the section 5 notice regulation imposes on the chemical industry. The chapter is organized to first provide the theoretical basis for assessing impacts, followed by a discussion of the kinds of costs the regulation imposes.

THEORETICAL EXPECTATIONS ABOUT IMPACTS[2]

Three classes of impacts that can be expected from the section 5 notice program are described below.

(1) Impacts on individual chemical firms. Income and profits may flow from one set of firms to another within the industry. It is generally thought that small chemical firms which rely on innovation are particularly threatened.

This is an area in which the impacts of section 5 notices might be great. It is important to mention that the impacts discussed here, up to and including the bankruptcy of an individual firm and the assumption of its production by other firms, do not cause any loss to society in the long run unless the industry becomes non-competitive. Economic theory suggests that there may be short-term disruptions and there may be severe costs to some people. But short-term disruptions should eventually disappear, and the losses to one group of people will be gains for another group. [We do not mean to imply that society should be unconcerned about changes in the distribution of benefits. We mean simply that we should recognize the difference between such changes and welfare losses.]

(2) Impacts on the chemical industry. These impacts include income and profit flows from the domestic chemical industry to foreign chemical industries and other domestic industries as well as changes in market structure in the chemical industry. To the extent that changes in market structure affect the productive efficiency and the flow of profits to the chemical industry, the economic analysis should offer evidence about the impact.

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[2] This analysis is concerned with the impacts on submitters of section 5 notices. A discussion of impacts on EPA and society can be found in Appendix D.

The reduction in chemical innovation and the increased costs of innovations that do survive could result in the replacement of chemicals by other materials in some applications, e.g. use of wood instead of plastic in a construction application. Thus, the hypothesis to test is that this replacement is not significant.

(3) Impacts on the U.S. as a whole. This includes any welfare losses due to inefficient production, changes in the balance of trade in chemicals, and changes in the balance of trade of products that consume chemicals.

We expect welfare losses[3] caused by inefficient production to be the most important economic impact of section 5 notices. Examples of welfare losses would be the delay in or lack of introduction of new chemicals into the marketplace.

The net effect of the regulations on the U.S. balance of trade in chemicals will depend on the form that new chemical regulation takes (or has taken in the case of Japan) in other major chemical-producing countries. If every other country had regulations identical to those of the U.S., we would expect no TSCA-prompted changes in the balance of trade. [Laws governing toxic substances already exist or will soon exist in other major industrial countries; Japan has a law, and the members of the European community are expected to pass laws by 1981 which conform to a model law.] Ideally, we would assess the relative barriers to the introduction of new chemicals posed by each of these laws, but the undefined aspects of each law or prospective law make it difficult to assess their consequences.

Economic theory indicates that the potential for disturbances in the balance of trade may have been greatly exaggerated because of the typically close relationship between the manufacturer and the customer. The specialty chemical manufacturers have described a situation in which frequent interaction between chemical firms and their customers occurs when a new chemical is first introduced.[4] It is hard to accept the idea that foreign firms introduce their chemicals here in a similar fashion, because the interactions with customers would be much more cumbersome and expensive, making their marginal cost curve higher. Consequently, increases in chemical imports and decreases in exports will occur only if some chemicals are never introduced here because of TSCA, but are introduced elsewhere.

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[3] A welfare loss can be contrasted to the income and profit flows from one set of firms to another discussed earlier. The latter represents a transfer from one set of economic actors to the other, but no loss to the economy as a whole. However, welfare loss occurs when there is a loss of productive efficiency in one sector of the economy without a counterbalancing increase in productive efficiency in another sector.

[4] Source: American Chemical Society, Chemistry in the Economy (Washington: ACS, 1973), p. 202; Comments of Reilly Tar and Chemical Company, March 21, 1979, pp. 9-17.

THEORETICAL BASIS OF SECTION 5 NOTICE IMPACTS

The impacts of section 5 suggested above flow from a key fact--the direct costs of regulation fall solely on new chemicals. Consequently, changes in the timing of introduction of new chemicals, production costs, and customer prices will be the focus of this analysis.[5/]

One way to identify these impacts is to focus on a single chemical which would have been introduced at time t, price p, and cost c before passing TSCA. After the passage of TSCA, a single chemical will be introduced at time t+t', price p+p', and cost c+c', where t', p', and c' are presumed to be positive. The magnitude of t', p', and c' will then determine the impacts of section 5 notices on individual firms in the chemical industry and on the U.S. economy.

IMPACT OF t'

First, consider the impact when the only change is that it takes longer to bring new products into the marketplace. Assuming that the only impact of section 5 notices is to delay the introduction of a new chemical by time t', an analysis can be performed to estimate the the result of this delay. Most interesting is the impact when a chemical is never introduced (t' = infinity). Because the chemical foregone is presumably more cost effective than the item it might replace, its lack of introduction causes society to suffer a welfare loss from producing inefficiently (which may or may not be offset by the welfare gain to society of not introducing a potential health hazard).

There are also distributional consequences when t' equals infinity: income flows from both the producers of the foregone new chemicals and the users of the chemicals to the producers of the items they would have replaced. To the extent these items are other chemicals, the chemical industry as a whole suffers no loss at any given level of national income. There is simply a redistribution among chemical companies. To the extent that the foregone chemicals would have replaced nonchemicals, e.g. glass, at any given level of national income the chemical industry loses income to other industries.

[5/] This presumes the main focus is on product innovation. Process innovations often result in the production of new intermediates. Because notices must be prepared for isolated intermediates, process innovations may also be inhibited. But because the success of the final product (if not on the new process) is already assured, we would expect the impacts of stifled process innovations to be much less than those of stifled product innovation.

The impact on industry profits of chemicals never being introduced is less clear. A new chemical could be patented and replace a competitively produced commodity chemical. In this case, all of the welfare gains would be absorbed by the producing firm's profits.[6] Therefore, the foregoing of a new chemical would mean a reduction in profits for the firm and for the industry. On the other hand, a new chemical could break up a monopoly, thereby reducing profits for the firm and the industry. In this case, the foregoing of a new chemical would prevent a decrease in profits for the industry.[7]

The situation would change somewhat if innovation were blocked in the United States but not in another country. Section 5 notices might also block import of the new chemical. If so, foreign manufacturers who use the new chemical would produce more inexpensively than American firms. If the final product were not subject to section 5 notice requirements and could be exported to the U.S., this could undercut American manufacturers. If the chemical were imported and replaced other imported chemicals, the net balance of trade would not change. If the new chemical replaced a domestically produced chemical, the balance of trade would change, and income would flow from the domestic chemical industry to the foreign chemical industry.

IMPACT OF c' AND p'

When t' is less than infinity, the new chemical would be introduced, but its cost would be raised by c' and its price by p'. Because of the increased price, the new chemical would not be used as widely as it otherwise would have been, and society would suffer a welfare loss like the one described above. Because of the decreased use of the new chemical, income would flow from new chemical producers to the producers of the goods or services the new product would have displaced.

In addition, there could be differential section 5 notice requirement barriers for importers and domestic producers. If so, these differential barriers would impose different costs on foreign and domestic producers, shifting income between foreign and domestic producers and changing the balance of trade.

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[6] In addition, welfare gains would be smaller than if the product were competitively priced.

[7] Even if the section 5 notice requirements were to inhibit the production of a large number of new chemicals in the short run, we would expect this to happen infrequently in the long run.

EMPIRICAL MANIFESTATION OF INCREASED COSTS AND DELAYS IN INTRODUCTIONS

Costs will increase (C+c') and the timing of introduction of some chemicals will be lengthened (t+t') when final section 5 regulations are promulgated because, for each new chemical entity, there will be associated regulatory costs. C' and t' can be translated into six "real world" factors: direct out-of-pocket costs, delays in the introduction of new chemicals, uncertainty regarding direct out-of-pocket costs, length of the delay, possible disclosure of trade secrets, and possible restrictive actions.

The direct out-of pocket cost can be considered to be (1) the pre-submission costs of planning the submission, collecting and organizing information, completing and submitting the notice; and (2) the post-submission costs of responding to requests for clarifications or additional information, appealing EPA decisions according to established Agency procedures, and pursuing legal challenges to Agency decisions. These costs are incurred and can be quantified on an individual company basis. For some companies, efforts to minimize these costs will include the added one time cost of restructuring their information data base.[8]

Delays in the introduction of new chemicals are the result of the statutory requirement for a 90-day review period and a possible extension of 90 days. In addition to these two requirements, the possibility for indefinite delay exists if a section 5(e) action is taken.

Uncertainty regarding the out-of-pocket costs focuses primarily on the possibility that the submitter will be required to submit additional information. Authorities under which additional information could be required include supplemental reporting, section 5(e) actions, or incomplete notice determinations.

Uncertainty regarding the length of delay derives from the gap in the statute which requires a complete notice for the 90-day clock to run. Without well-defined procedures for determining if submissions meet the criteria for a notice, companies will always be concerned about lengthy delays. Uncertainty will peak if delay occurs precisely at the moment when a competitor introduces an alternative product that captures the first firm's anticipated market.

Uncertainty about possible trade secret disclosure. The act requires that within five days of receiving a submission EPA place a notice of receipt in the Federal Register. Although efforts to disguise the information in the notice are substantial (as we discuss later), the possibility exists that the notice will not sufficiently protect trade secrets. There is also some concern that a Freedom of Information Act request will be improperly handled causing disclosure.

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[8] ADL estimated the pre-submission direct out-of-pocket costs for the January 10, 1979 proposal and the October 16, 1979 reproposal. Using the ADL methodology, ICF estimated these costs for the minimium reporting guidance option, processor reporting, and importer reporting. For details about the cost estimates the reader should refer to the ADL reports and Appendix A to this report.

The final cost is uncertainty about regulatory actions. The entire process is affected by the concern that a chemical will be regulated by EPA. Consistent action by the agency will reduce this uncertainty. This cost often overwhelms the others because it dictates strategies concerning pre-submission decisions about what data to provide. In the worst case, the regulatory action is a 5(f) decision causing infinite delay.

PROBLEMS WITH COST ESTIMATION

At the present time, not all of the costs to submitters readily translate into dollars. Even for the costs which would generally be specified in dollars (i.e., direct out-of-pocket costs), information does not exist which adequately captures the pre-submission and post-submission expected out-of-pocket costs for a variety of industry segments. As ICF explains later, it is clear that uncertainty costs far outweigh direct out-of-pocket costs within all industry segments. For some firms in each segment, direct costs may outweigh uncertainty; but this is the exception. In particular, industry experts steadfastly maintain that direct out-of-pocket costs are not the most important type of cost. Because these out-of-pocket costs readily translate into dollars, previous attempts to estimate the costs of complying with section 5 requirements have focused on pre-submission out-of-pocket costs. It should not be inferred, however, that because pre-submission, out-of-pocket costs are the only costs that currently lend themselves to monetization, that they are necessarily the most important costs.

Chapter 5 quantifies in dollars the pre-submission, out-of-pocket costs when existing data permit. Otherwise, costs are presented ordinally.

SUMMARY

Section 5 imposes six kinds of costs on submitters which can be grouped into pre-submission and post-submission categories as follows:

(1) Before the notice is submitted, the submitter incurs the following pre-submission costs:

- out-of-pocket costs of planning the submission, collecting and organizing information, and completing and submitting the notice; and
- time delay costs, as defined by the delays in the commencement of manufacturing attributable to completing the notice.

(2) After the notice is submitted, the submitter could incur the following post-submission costs:

- additional out-of-pocket costs in responding to requests for clarifications or additional information, appealing EPA decisions within established Agency procedures, or pursuing legal challenges to Agency decisions;
- additional delays in the commencement of manufacture for the same reasons cited above;
- the disclosure of trade secrets; and
- restrictions placed on how the chemical can enter commerce.

CHAPTER 5

ANALYSIS OF COMPREHENSIVE PROGRAM OPTIONS

The magnitude of the costs imposed by section 5 varies with the regulatory option chosen. This chapter analyzes the costs of each regulatory option across the main issues:

- confidentiality;
- customer contact;
- importer definition;
- importer contact of foreign manufacturer/supplier;
- exporter reporting;
- supplemental reporting;
- insufficient submissions;
- processor reporting; and
- possession or control.

Three comprehensive program options (CPOs) were constructed by EPA by selecting one regulatory option for each of the nine issues.

The three CPOs are defined in Exhibit 5-1. The nine issues were analyzed according to the cost dimensions discussed in Chapter 4:

- pre-submission
  - out-of-pocket costs, and
  - delay costs; and
- post-submission
  - out-of-pocket costs,
  - delay costs,
  - potential trade secret disclosure costs, and
  - restrictive action costs.

Costs for each CPO were constructed from the costs of the option appropriate to that CPO for each of the nine issues. These costs were compared on a monetized basis when sufficient data were available. Otherwise, they were compared on an ordinal basis. ICF developed the ordinal comparisons because the only costs that lent themselves to monetization were the pre-submission out-of-pocket costs. To compare the magnitude of the non-monetized costs, ICF employed an ordinal ranking system.

EXHIBIT 5-1

SUMMARY OF COMPREHENSIVE PROGRAM OPTIONS*

Issues	CPO 1	CPO 2	CPO 3
Reporting Requirement	Minimum Guidance	EPA Reproposal	EPA Proposal
Confidentiality			
Assert	Item-by-Item	Category	Category
Substantiate	Series of questions	Reproposal questions	Series of questions
Timing	5(d)(2) at submission	All at submission	All at submission
Generic	None	4 categories	4 categories
Chemical ID Timing	Manufacturing	Manufacturing	Submission
Chemical ID Inventory	Generic	Specific	Specific
Customer Contact	None	Unknown Uses	Proposal
Importer Definition	Principal Importer	Combined responsibility (proposal)	Combined responsibility (proposal)
Upstream Contact	Health and environmental effects data and risk assessments only	Form based on reproposal	Proposed form
Exporter	Section 8 notice (coverage equivalent to proposal; authority differs)	Reproposal	Proposal
Supplemental Reporting	Case-by-Case	Reproposal	Proposal
Insufficient Submissions	Right to invalidate; no procedures	January 1979 proposal	Time limit; appeal procedures
Processor Reporting	Processor reporting under section 8	Processor reporting for exempt substances (section 5)	Manufacturer and importer reporting
Possession or Control	Subsidiaries only, same venture	Entire corporate hierarchy, same venture	Entire corporate hierarchy, any venture

*These options are explained in subsequent pages. In-depth analysis of each issue is found in Part II of this document.

The system assigned values according to the following rules:

1. Regulatory options imposing no costs to submitters were assigned a zero rating.
2. Regulatory options which according to data and logic imposed the lowest costs were assigned a 1.
3. Regulatory options imposing higher costs were given higher rankings.
4. Regulatory options which according to data and logic imposed equal costs were assigned equal ratings.

In the remainder of this chapter we first discuss the costs of reporting requirements for the three comprehensive program options. Next we summarize the regulatory options and costs for each of the nine regulatory issues. This is followed by a discussion of the inter-relationships between the nine issues and their costs. The chapter closes with a discussion of the costs imposed by the comprehensive program options on domestic manufacturers producing for domestic consumption, importers, foreign manufacturers, exporters, and processors.

The issues analyzed here are multi-faceted and complex. In the interests of clarity of presentation, the summaries of the CPOs and the nine issues are highly simplified. Complete discussion of each CPO and the nine issues can be found in Part II of this report. A presumption of familiarity with the January 10, 1979 proposal and October 16, 1979 reproposal has been made.

REPORTING REQUIREMENTS

In addition to the nine issues, the costs of the reporting requirements as explained below, were considered. CPO 1 imposes the least reporting requirements and CPO 3 the most. This does not mean that CPO 1 is least costly.

Pre-submission Costs

Exhibit 5-2 contains the cost summary for reporting requirements. The dollar estimates for pre-submission out-of-pocket costs were derived using a methodology similar to that used by ADL.[9] Presubmission delay costs increase from CPO 1 through CPO 3 because the more information needed to comply with the reporting requirements, the longer it will take to gather the necessary information and submit the section 5 notice.

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[9] Arthur D. Little, Inc. (ADL), Impact of TSCA Proposed Premanufacturing Notification Requirements (Cambridge, Mass: December 1978).

EXHIBIT 5-2

COMPARISON OF COSTS ATTRIBUTABLE TO NOTIFICATION REQUIREMENTS

Cost	CPO 1 Minimum Guidance	CPO 2 10/16/79 Reproposal	CPO 3 1/10/79 Proposal
Pre-submission costs			
Out-of-pocket costs	$1,000-7,500[a]	$1,200-8,900[b]	$3,700-42,000[c]
Delay	1	2	3
Post-submission costs			
Potential out-of-pocket	3	2	1
Potential delay	3	2	1
Potential trade secret disclosure	1	2	3
Potential restrictions	1	2	3
Coverage	1	1	1

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[a] Appendix A to this report in "Appendix: Volume 1," p. A-25.

[b] Arthur D. Little, Inc., Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, (Cambridge, Mass.: September 1979), p. 38.

[c] Arthur D. Little, Inc., "Impact of TSCA Proposed Premanufacturing Notification Requirements," (Cambridge, Mass.: December 1978), p. V-17.

Note: for ordinal estimates, 0 = no cost, 1 = lowest cost, 2 = next lowest costs, etc.

Post-Submission Costs

Post-submission out-of-pocket costs decrease from CPO 1 through CPO 3 because the probability that EPA will require additional existing information to evaluate the submission decreases with the breadth of the initial reporting requirements. That is, the more existing information required at the time of submission, the less additional existing information will be needed after submission. Post-submission delay also decreases from CPO 1 through CPO 3 because the less defined and less comprehensive the notice requirements, the more likely it is that the notice period will be extended for up to an additional 90 days in order to reach additional existing data.

The risk of potential trade secret disclosure increases from CPO 1 through CPO 3 because the broader the initial reporting requirements, the more confidential business information is likely to be submitted. The risk of trade secret disclosure is the product of the quantity of trade secrets submitted multiplied by the probability of disclosure (as defined by the confidentiality policy). Therefore, risk of trade secret disclosure increases with the breadth of reporting requirements.

As the initial reporting burden increases, some potential new chemicals will not be able to meet the more burdensome notice requirements. When submitters choose not to subject these chemicals to section 5 review because the review process is considered too burdensome, the resultant decision not to enter the market becomes a *de facto* restriction on that chemical entering commerce.

In addition, the changes in explicit EPA regulatory decisions that are brought about by increasing the initial reporting burden is an issue that needs consideration. The rationale for increased information must be improved decision making. In the case of EPA regulatory decisions (i.e., the decision to initiate a 5(e) or 5(f) action), the additional information must sometimes lead to changed decisions. In some cases, chemicals which would not have been subjected to some restrictions without the additional information now would be. In other cases, chemicals which would have been subjected to some restrictions without the additional information now would not be. The combination of voluntary submitter decisions not to enter the market and possible changed EPA regulatory decisions contribute to fewer new chemicals coming to market as initial reporting requirements increase from CPO 1 through CPO 3.

Coverage

The reporting requirements for the three CPO's do not differ on coverage of manufacturers. Any potential coverage differences in customer contact, importers, exporters, or processors are addressed later in this chapter.

ISSUE 1. CONFIDENTIALITY

Provisions relating to the confidentiality of submitted information attempt to reconcile the concerns of business that trade secrets will be disclosed with public concerns that adequate information on the hazardous nature of the chemicals should be made available. The key elements of this issue are the method for asserting the claim of confidentiality (assert), the method for substantiating the claim (substantiate), the timing of the claim (timing), the manner in which the information is masked (generic), the timing of identification of the chemical (chem ID timing), and the type of name by which the chemical will be placed on EPA's inventory (chem ID inventory). The CPOs are defined across these elements as shown below:

Element	CPO 1	CPO 2	CPO 3
Assert	Item by Item	Category	Category
Substantiate	Minimum Guidance	Reproposed Questions	Minimum Guidance
Timing	5(d)(2) at Submission	All at Submission	All at Submission
Generic	None	4 Categories	4 Categories
Chem ID Timing	Manufacture	Manufacture	Submission
Chem ID Inventory	Generic	Specific	Specific

Costs to the submitter are summarized in Exhibit 5-3 and are discussed below.

Method and Timing of Assertion and Substantiation

Pre-submission Costs. In assessing the pre-submission out-of-pocket costs associated with confidentiality, the benchmark is an ADL estimate (assuming a claim is made) derived while costing the reproposal.[10] The ADL cost ranges were specified for "a generalized method of asserting and substantiating claims of confidentiality." The ADL estimate for pre-submission out-of-pocket costs is assumed to apply to both CPO 2 and CPO 3, because they differ only on the substantiation questions. The pre-submisson out-of-pocket costs are less for CPO 1, because not all information asserted as confidential needs to be substantiated at the time of submission. These same relationships hold for pre-submission delays: delays for CPO 1 are less than delays for CPO 2 and CPO 3, because not all items asserted as confidential need to be substantiated at the time of submission.

Post-Submission Costs. CPO 1 has larger post-submission out-of-pocket costs than CPO 2 or CPO 3 because of the potential need to substantiate some items after submission. There are no post-submission delays associated with

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[10] Arthur D. Little, Inc., Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form (Cambridge, Mass.: September 1979), p. 52.

EXHIBIT 5-3

COMPARISON OF COSTS ATTRIBUTABLE TO CONFIDENTIALITY PROVISIONS[a]

Cost	CPO 1 Assert: Item by Item Substantiate: Interim questions Timing: 5(d)(2) at submission Generic: none Chem ID Timing: Mfg Chem ID Inventory: Generic	CPO 2 Assert: Category Substantiate: Reproposal questions Timing: All at submission Generic: 4 Categories Chem ID Timing: Mfg Chem ID Inventory: Specific	CPO 3 Assert: Category Substantiate: Interim questions Timing: All at submissio Generic: 4 Categories Chem ID Timing: Submissio Chem ID Inventory: Specific
Method and Timing of Assertion and Substantiation			
Pre-submission costs			
Out-of-Pocket Costs	less than $900-6400	$900-6400[b]	$900-6400
Delay	1	2	2
Post-submission costs			
Potential out-of-pocket	2	1	1
Potential delay	0	0	0
Potential trade secret disclosure	1	2	2
Potential restrictions	0	0	0
Coverage	1	1	1
Generic Requirements			
Pre-submission costs			
Out-of-pocket costs	0	1	1
Delay	0	1	1
Post-submission costs			
Potential out-of-pocket	0	1	1
Potential delay	0	0	0
Potential trade secret disclosure	0	1	1
Potential restrictions	0	0	0
When to Disclose Chem ID			
Potential trade secret disclosure	1	1	2
How to Place on Inventory			
Potential trade secret disclosure	1	2	2

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[a] Assume that a confidentiality claim is made.

[b] "Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form" ADL, Inc., September 1979, p. 52.

Note: For ordinal estimates, 0 = no cost, 1 = lowest cost, 2 = next lowest.

asserting and substantiating confidential items because policies related to the withholding and disclosure of confidential business information do not have any effect on whether the 90-day notice period will be extended. Potential trade secret disclosure is higher under CPOs 2 and 3 than under CPO 1 because of the timing of substantiation. Under CPOs 2 and 3, it is possible that there will be some confidentiality claims that are not sufficiently substantiated which can conceivably enter the public domain. Because there is no initial substantiation and no possibility of not sufficiently substantiating at this point under CPO 1, the opportunity for disclosure decreases.

We assume that a submitter's motive in voluntarily initiating restrictions will not stem solely from considerations of confidentiality. Of course, it is possible that submitters might not submit new chemicals for section 5 review, but the underlying reason for refraining to do so is more likely to be the appreciable costs of trade secret disclosure.

Coverage

There are no coverage differences attributable to any of the confidentiality provisions.

Generic Requirements

Because there are no generic requirements under CPO 1, there are no costs under the generic heading.

Pre-submission Costs. Pre-submission out-of-pocket costs under CPOs 2 and 3 involve developing generic masking for items asserted as confidential. Development of such generic masks would also carry some pre-submission delay.

Post-Submission Costs. CPOs 2 and 3 carry potential post-submission out-of-pocket costs because additional details related to generic masking may have to be negotiated between the submitter and EPA. CPOs 2 and 3 also carry some risk of potential trade secret disclosure, because generically masked information might be used by others to uncover trade secrets. There are no post-submission delays or potential restrictions resulting from generic requirements.

Other Confidentiality Provisions

Other provisions for confidentiality concern how and when chemical identity, as part of a health and safety study, would be disclosed. Cost differences between the comprehensive program options relate only to potential trade secret disclosure. The risk of trade secret disclosure depends on the CPO. CPO 3 (disclosure at submission) carries a greater risk of disclosure than do CPOs 1 or 2. CPO 1 (add to inventory generically) carries a lesser risk of disclosure than CPO 2 or 3 (add to inventory by specific chemical identity).

ISSUE 2. CUSTOMER CONTACT

In some circumstances, new chemical customers could provide data in such areas as worker exposure, waste disposal, and environmental release. The CPOs vary in terms of the number of customers contacted and the amount of information sought:

- CPO 1: no customer contact provisions;
- CPO 2: the reproposal asks for reports on approximate production quantities and number of customers for which use is unknown [note: a recent variation on this general approach is to report the expected use distribution broken down by quantities and number of customers]; and
- CPO 3: the initial proposal (mandatory contact for a very broad definition of customers and mandatory submission of customer lists).

Costs are addressed below. Costs to submitters and costs to customers are both considered and are summarized in Exhibit 5-4.

Cost to Submitters

Pre-submission Costs. Pre-submission out-of-pocket costs increase from CPO 1 through CPO 3. Mandatory contact for all of the categories of customers specified in CPO 3 is clearly more costly than providing use information. There are pre-submission delay costs for CPO 3 because mandatory contact will consume additional time before the notice can be submitted.

Post-Submission Costs. There are post-submission costs for CPO 2, because this is the only option where EPA would go back to the submitter and ask for information about some customers as a direct result of reporting requirements about customer uses. EPA could also ask for customer information under CPO 1, but the reporting requirements under CPO 1 are not as likely to generate use information which would trigger these requests. Furthermore, because there are no customer contact provisions under CPO 1, any such requests to submitters would have to be considered costs of supplemental reporting. Under CPO 3, all out-of-pocket costs have been incurred at the time of submittal. Thus, only CPO 2 has potential post-submission out-of-pocket costs directly attributable to customer contact.

Post-submission delays are more likely under CPO 3 than under CPO 2. The requirement under CPO 3 that submitters must contact customers and request that they submit customer forms may result in EPA's invoking section 5(c) more often in order to receive all of the relevant information on which to base a decision. EPA may also, have to use supplemental reporting to obtain receiving information from customers under this option. Under CPO 2, information needs from customers are more focused, resulting in infrequent need for 5(c).

EXHIBIT 5-4

COMPARISON OF COSTS ATTRIBUTABLE TO CUSTOMER CONTACT

Cost	CPO 1 (none)	CPO 2 (reproposal)	CPO 3 (proposal)
Pre-submission costs			
Out-of-pocket costs	0	1	2
Delay	0	0	1
Post-submission costs			
Potential out-of-pocket	0	1	0
Potential delay	0	1	2
Potential trade secret disclosure	0	0	1
Potential restrictions	0	1	2
Coverage	0	1	2
Cost to customers	0	1	2

Note: 0 = no cost, 1 = lowest cost, etc.

Costs associated with potential trade secret disclosure are only incurred under CPO 3. Under CPO 3, mandatory contact, particularly to potential rather than actual customers, coupled with the mandatory submission of a customer list, increases the problem of trade secret disclosure.

Potential restrictions on how chemicals can enter commerce are likely to increase from CPO 1 to CPO 3. Voluntary submitter actions to refrain from submitting chemicals to section 5 review could increase as customer contact provisions grow. The impact of the additional information on explicit EPA regulatory decisions is not clear and could result in changes in either direction. The combination of voluntary submitter actions and changed EPA explicit regulatory decisions increases the potential cost of restrictive action as customer contact provisions become more burdensome.

Coverage. The options move toward broader coverage. CPO 1 has no customer contact policy, so the definition of customer is not a factor. CPO 2 is limited to those customers with firm commitments and CPO 3 reaches beyond this to potential customers with less than firm commitments.

Cost to Customers. Under CPO 1 there are no costs to customers. Under CPO 2, there are costs only when EPA makes inquiries to selected customers based on information provided by the submitter on customer use. Under CPO 3, there are optional information requests to customers, and responses to them could be quite lengthy. Thus, the costs to customers increase from CPO 1 through CPO 3.

ISSUES 3 and 4. IMPORTER PROVISIONS

The issue of importer definition deals with designating the entity which must comply with section 5 requirements for imported chemicals. The CPOs vary in terms of the specific identity of the importer and the amount of information requested of the foreign manufacturer:

Issue	CPO 1	CPO 2	CPO 3
Definition of Importer	Principal Importer	Combined Responsibility (Proposal)	Combined Responsibility (Proposal)
Upstream Contact	Mandatory Health and Safety Data Only	Mandatory Revised Information Request	Mandatory 1/10/79 Form

The cost of these alternatives is addressed below and summarized in Exhibit 5-5.

Definition of Importer

Pre-submission Costs. Pre-submission out-of-pocket costs to importers are provided in Exhibit 5-5. These costs were derived by applying the ADL cost-estimating methodology to the reporting requirements for importers under

EXHIBIT 5-5

COMPARISON OF COSTS ATTRIBUTABLE TO IMPORTER PROVISIONS

Cost	CPO 1 def: principal importer upstream: mandatory health and safety data	CPO 2[a] def: combined responsibility upstream: mandatory revised information request	CPO 3[a] def: combined responsibility upstream: mandatory 1/10/79 form
Definition of Importer			
Pre-submission costs (Importer)			
Out-of-pocket	$800-7500[b]	$900-8900[c]	$2300-26,700[d]
Delay	1	2	3
Post-submission costs			
Potential out-of-pocket	3	2	1
Potential delay	3	2	1
Potential trade secret disclosure	1	2	3
Potential restrictions	1	2	3
Coverage	1	2	2
Upstream Contact			
Pre-Submission Costs			
Out-of-pocket (Foreign Mfr.)	$300-1500[e]	$1800-7200[f]	$3000-11,600[g]
Delay	1	2	3
Post-submission costs			
Potential out-of-pocket	3	2	1
Potential delay	3	2	1
Potential trade secret disclosure	1	2	3
Potential restrictions	1	2	3
Coverage	1	1	1

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[a] Assumes parties will make a good faith effort to comply with the definition.

[b] Minimum is minimum guidance form less $200 for cost of completing a minimum guidance section II-A. Maximum is maximum cost of complete minimum guidance form.

[c] Minimum is minimum cost of reproposed form less $300 for cost of completing a reproposed section II-A. Maximum is maximum cost of reproposed form.

[d] Minimum is minimum cost of completing sections I, II-A, II-D of proposed form. Maximum is maximum cost of completing section I, II-A, II-C, II-D, III-A, III-B, III-C of proposed form.

[e] Minimum is minimum of completing section III-B of the reproposed form. Maximum is maximum cost of completing section III-B of the reproposal.

[f] See Part II, Chapter 4, Exhibit 4-3 for explanation.

[g] Minimum is minimum cost of completing Section I-A, I-B, I-C, I-D, II-A, II-B, II-C of January 1979 Proposed Foreign Manufacturer/Suppliers Form as approximated by comparable sections of proposed domestic form. Maximum is maximum cost of same sections (See Part II, Chapter 4, Exhibit 4-3 for more details.

Note: For ordinal estimates, 1 = lowest cost, 2 and 3 = next lowest costs, respectively.

each of the comprehensive program options. Pre-submission delays are assumed to be in proportion to the breadth of reporting requirements and, therefore, increase from CPO 1 through CPO 3.

Post-Submission Costs. Potential post-submission out-of-pocket costs decline from CPO 1 through CPO 3 because potential requests for additional information are inversely related to the scope of the initial reporting requirements. The more information that is provided with the initial notice, the less additional information will be needed to make regulatory decisions. Potential post-submission delay also decreases from CPO 1 through CPO 3, because the probability of EPA initiating 5(c) action decreases with the increased quantity of information provided by the initial submission. Potential trade secret disclosure increases from CPO 1 through CPO 3, because, the more information that is provided with the initial submission, the more likely it is that trade secrets are included and, therefore, subject to disclosure independent of the confidentiality policy.

The potential for submitters to decide not to introduce a new chemical into commerce is likely to increase from CPO 1 to CPO 3. As reporting requirements for importers become more stringent, submitters are more likely to voluntarily not submit some chemicals to section 5 review. These voluntary decisions are responsible for the increasing cost of possible restrictive actions.

Coverage. CPO 1 results in notice submission from the single most knowlegeable importer. The combined responsibility policy under CPOs 2 and 3 applies to a broader set of firms than just the single defined importer.

Upstream Contact

Presubmission Costs. The pre-submission costs to the foreign manufacturer/supplier are estimated assuming that the foreign manufacturer will respond to requests for information. Pre-submission out-of-pocket costs are estimated by applying the ADL methodology to the appropriate reporting requirements for foreign manufacturers/suppliers. Pre-submission delay is assumed to be proportional to the scope of reporting requirements.

Post-Submission Costs. The logic for the ordinal rankings of post-submission costs is identical to the logic presented for post-submission costs for the definition of importer. Potential post-submission out-of-pocket costs and delays decrease as the breadth of initial reporting requirements increase. Potential trade secret disclosure and restrictive actions increase as more information is required in the initial notice.

Coverage. There are no coverage differences; all three comprehensive program options reach the identical set of foreign manufacturers/suppliers.

ISSUE 5. EXPORTER PROVISIONS

The issue of exporter responsibility deals with the manufacture and transport of chemicals for export. The CPOs vary from no reporting responsibility to the same responsibility as domestic manufacturers who distribute domestically. The CPO exporter options, applicable only to domestic manufacturers/suppliers producing solely for export, are as follows:

- CPO 1: submit section 8 notice equivalent to October 16, 1979 reproposal;
- CPO 2: submit section 5 notice equivalent to October 16, 1979 reproposal; and
- CPO 3: submit section 5 notice equivalent to January 10, 1979 notice.

Exhibit 5-6 contains the cost summaries, described in more detail below.

Pre-submission Costs

Pre-submission out-of-pocket costs are shown in Exhibit 5-6. These estimates were derived by applying the ADL cost-estimating methodology to the appropriate reporting requirements, as specified in the exhibit. Presubmission delay is assumed to be proportional to the breadth of notice requirements. Therefore, pre-submission delay under CPO 3 is greater than under the other two options.

Post-Submission Costs

No post-submission out-of-pocket costs related to section 5 are attributable to CPO 1, because no action would be taken under section 5 rule.[11] Post-submission out-of-pocket costs are higher under CPO 2 than under CPO 3 because EPA is more likely to request additional information under CPO 2. Also, the potential for post-submission delay is greater under CPO 2 because the less extensive the initial reporting requirements, the more likely are 5(c) actions.

The potential for trade secret disclosure and the potential for restrictive action increase as initial reporting requirements grow more extensive. More trade secrets are assumed to be submitted as reporting requirements increase. Also, submitters will voluntarily restrict the flow of new chemicals into commerce as the burden of section 5 grows.

Coverage

CPO 1 applies to a smaller set of exporters because there is a small business exemption under section 8: manufacturers and processors with total annual sales under $1 million are generally exempted from section 8 rules. There are no other coverage differences between the definitions. All apply to domestic production solely for export.

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[11] We recognize that section 8 rules have costs associated with them. However, if section 8 authority is used, there is no section 5-related cost. Since we are analyzing section 5 impacts (see Chapter 2), we cannot consider section 8-related costs.

EXHIBIT 5-6

COMPARISON OF COSTS ATTRIBUTABLE TO EXPORTER PROVISIONS

Cost	CPO 1 (Section 8 Notice)	CPO 2 (Must Submit 10/16/79 Notice)	CPO 3 (Must Submit 1/10/79 Notice)
Pre-Submission Costs			
Out-of-pocket	$1200-8100[a]	$1200-8100[b]	$2500-40,300[c]
Delay	0	1	2
Post-submission costs			
Potential out-of-pocket	0	2	1
Potential delay	0	2	1
Potential trade secret disclosure	0[d]	1	2
Potential restrictions	0[d]	1	2
Coverage	1	2	2

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[a] Assumes section 8 reporting requirements are identical to the October 16 requirements.

[b] Minimum is minimum cost of October 16 form less minimum cost of completing parts II-B and II-C. Maximum is maximum cost of October 16 form less maximum cost of completing part II-C.

[c] Minimum is minimum cost of January 10 form less minimum cost of completing parts II-C and II-D. Maximum is maximum cost of January 10 form less maximum cost of completing part II-D.

[d] Although there may be costs here, they would not be attributable to section 5. As mentioned in Chapter 2, we are analyzing the costs of section 5. Therefore, a rule based on section 8 authority has no section 5-related cost.

Note: For ordinal estimates, 0 = no cost, 1 = lowest cost, 2 = next lowest cost.

ISSUE 6. SUPPLEMENTAL REPORTING

Supplemental reporting would require information in addition to the data included in the original submission. The CPOs vary according to the type of additional information and the circumstances under which it could be required:

- CPO 1: section 8 rules on a case-by-case basis;
- CPO 2: reproposal of October 16, 1979 (section 8 letter writing authority with reasonably well defined criteria and appeal mechanism); and
- CPO 3: proposal of January 10, 1979 (section 8 letter writing authority with less well-defined criteria).

Costs are summarized in Exhibit 5-7 and are discussed below.

Pre-submission Costs

There are no pre-submission costs.

Post Submission Costs

Submitters are required to provide the most post-submission information under CPO 3 and the least under CPO 1.

Potential post-submission delays can occur through 5(c) or 5(e) actions. The probability of a 5(c) action to extend the notice period is assumed to be independent of the procedures for supplemental reporting. The probability of a 5(c) action is likely to be a function of the quality and quantity of information initially submitted and the complexity of the evaluation decision based on available chemical-specific information. The probability of a 5(e) action is greater under CPO 1 than under the other two options because EPA might use 5(e) actions under CPO 1 because there is no other way to obtain additional information. Therefore, the potential for post-submission delay is greater under CPO 1 than under the other two options.

The relative costs for potential trade secret disclosure and potential restrictions are based on the principle that the more information which can be submitted under supplemental reporting, the higher likelihood it is that:

- more trade secrets will be submitted and, therefore, subject to possible disclosure; and
- additional information requirements create a higher hurdle for submitters and may result in a voluntary reduction in the number of chemicals submitted to section 5 review. Also, the additional information may result in changes to specific regulatory decisions.

EXHIBIT 5-7

COMPARISON OF COSTS ATTRIBUTABLE TO SUPPLEMENTAL REPORTING

Cost	CPO 1 (section 8 case-by-case)	CPO 2 (October 16)	CPO 3 (January 10)
Pre-Submission Costs			
Out-of-pocket	0	0	0
Delay	0	0	0
Post-submission costs			
Potential out-of-pocket	1	2	3
Potential delay	2	1	1
Potential trade secret disclosure	1	2	3
Potential restrictions	1	2	3
Coverage	1	1	1

Note: For ordinal estimates, 0 = no cost, 1 = lowest cost, 2 and 3 = next lowest costs, respectively.

Coverage

There are no coverage differences among the three supplemental reporting options.

ISSUE 7. INSUFFICIENT SUBMISSIONS

The issue of insufficient submissions deals with the failure of submissions to meet the statutory requirements and errors which impede notice review. The CPOs vary in their characterization of the deficiencies, prescribed time delays, and appeal processes:

- CPO 1: case-by-case determination, no general procedures;
- CPO 2: the proposed policy of January 10, 1979; and
- CPO 3: correction of errors, specification of inadequacies in submissions, and appeal procedures.

Exhibit 5-8 contains a summary of costs for insufficient submissions policy. Costs for CPO 1 were estimated assuming that submitters and EPA would behave identically under CPOs 1 and 3. It is recognized, however, that under CPO 1, EPA would have discretion to deviate from the policy defined by CPO 3, which would create additional uncertainty for submitters.

Presubmission Costs

Assuming the pre-submission period is defined by when the submitter submits an initial piece of paper which it believes is a section 5 notice, rather than with the submission of a notice which meets the statutory criteria, there are no pre-submission costs associated with any of the alternatives.

Post-Submission Costs

Out-of-pocket costs are the same under all three options because roughly the same submissions would be found incomplete or invalid under all three options, and the same corrections would be made. Delay associated with CPO 2 is greater than CPO 3; under CPO 3, the finding must be made within the first 30 days, but there is no such restriction under CPO 2. Also, the notice clock is suspended under CPO 2 for minor deficiencies provided they are corrected within a specified time. The clock is not stopped for minor deficiencies under CPO 3. For purposes of this analysis, delays attributable to CPO 1 are assumed to be identical to delays under CPO 3. Delays under CPO 1, however, could be greater or lesser than under CPO 3, because of uncertainty about the way in which CPO 1 would be implemented.

The three options are assumed to require the same additional information. Thus, they do not differ in their potential for trade secret disclosure or their potential to result in restrictive actions.

EXHIBIT 5-8

COMPARISON OF COSTS ATTRIBUTABLE TO INSUFFICIENT SUBMISSIONS

Cost	CPO 1[a] (Case-by-case determinations no general procedures)	CPO 2 (Proposed 1/10/79)	CPO 3 (Time Limit; Appeal Procedures)
Pre-Submission Costs[b]			
Out-of-pocket	0	0	0
Delay	0	0	0
Post-submission costs			
Potential out-of-pocket	1	1	1
Potential delay	1	2	1
Potential trade secret disclosure	1	1	1
Potential restrictions	1	1	1
Coverage	1	1	1

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[a] In estimating costs, the behavior of submitters and EPA are assumed to be identical under CPOs 1 and 2. It is recognized, however, that under CPO 1, EPA would have discretion to deviate from the policy defined by CPO 2, which would create additional uncertainty for submitters.

[b] Defined by when submitter submits notice, not when notice period begins.

Note: For ordinal estimates, 0 = no cost, 1 = lowest cost, 2 = next lowest cost.

Coverage

There are no coverage differences attributable to the options.

ISSUE 8. PROCESSOR REPORTING

The issue of processor reporting deals with the reporting of chemicals previously exempt from reporting under TSCA. The CPO's vary from a section 8 requirement to the January 10 proposal.

- CPO 1: processors submit section 8 notices;
- CPO 2: processors submit section 5 notice equivalent to October 16, 1979 reproposal; and
- CPO 3: manufacturers and importers submit section 5 notice equivalent to January 10, 1979 (no separate processor).

Exhibit 5-9 contains the cost summaries which are explained below.

Pre-submission Costs

Pre-submission out-of-pocket costs are shown in Exhibit 5-9. The estimates were derived by applying the ADL cost-estimating methodology to the appropriate reporting requirements. Pre-submission delays increase as more information is initially requested for review. Because CPO 3 requests more information than CPO 2, delays under CPO 3 are greater than those under the CPO 2.

Post-Submission Costs

Because CPO 1 requires reporting under section 8, no post-submission costs arise. Post-submission out-of-pocket costs and delay costs are greater under CPO 2 than under CPO 3 because those potential costs decrease with the stringency of initial reporting requirements.

The potential for trade secret disclosure and restrictive actions increases as initial reporting requirements grow more stringent. More trade secrets are assumed to be submitted as reporting requirements increase, and increased reporting requirements are expected to lead to more voluntary restrictive actions by submitters (i.e., a decision not to market). Also, the increased reporting requirements presumably will lead to some changed regulatory decisions for some specific chemicals, although these changes could be in either direction.

Coverage

CPO's 1 and 2 cover all processors whether they are the manufacturer (or importer) or separate entities. CPO 3 covers only processors who are manufacturers or importers; coverage does not extend to separate processors.

EXHIBIT 5-9

COMPARISON OF COSTS ATTRIBUTABLE TO PROCESSOR REPORTING

Cost	CPO 1 (Section 8 Reporting)	CPO 2 (August 1980 Proposal) October 16 form	CPO 3 (January 10 Proposal) January 10 form
Pre-Submission Costs			
Out-of-pocket	724-4,450	$1,200-8,900	$3,700-42,000
Delay	1	1	2
Post-submission costs			
Potential out-of-pocket	0	2	1
Potential delay	0	2	1
Potential trade secret disclosure	1	1	2
Potential restrictions	0	1	2
Coverage	2	2	1

Note: 0 = none, 1 = lowest cost, 2 = next lowest cost.

ISSUE 9: POSSESSION OR CONTROL

The issue of possession or control arises from the requirement that all test data in the possession or control of the submitter be included with the section 5 notice. The CPOs vary by the extent of the possession or control definition, horizontally, vertically, and by involvement in the current venture.

- CPO 1: possession or control of test data limited to the submitter and the companies controlled by the submitter that are involved in the current venture;
- CPO 2: possession or control of test data limited to the submitter and the parents, subsidiaries, and other companies controlled by the parent company which are involved in the current venture. (i.e., any corporate entity in the corporate hierarchy involved in the current venture); and
- CPO 3: possession or control limited to submitter and parents, subsidiaries, and other companies controlled by the parent company which are not necessarily involved in the current venture (i.e., all corporate entities in the corporate hierarchy).

Costs are summarized in Exhibit 5-10 and are described below.

Pre-submission Costs

The further the submitter must search within its own corporate structure, the greater the pre-submission costs in both time and money. Thus, the costs of pre-submission possession or control increase from CPO 1 through CPO 3.

Post-Submission Costs

Potential post-submission out-of-pocket costs decrease with an increasing scope of the definition of possession or control, because the more information required at time of submission, the less post-submission information will be required.

Post-submission delay decreases as the scope of the definition of possession or control increases, because delaying actions are less likely when there is additional information provided initially.

The potential for trade secret disclosure increases with the scope of the definition, because more information must be submitted.

The relationship between potential restrictive actions and possession or control is similar. The further submitters are required to search, the more likely it is that some submitters will choose not to enter the market because the perceived costs of notice requirements are too great.

EXHIBIT 5-10

COMPARISON OF COSTS ATTRIBUTABLE TO POSSESSION OR CONTROL

Cost	CPO 1 (entities controlled by submitter, same venture)	CPO 2 (whole hierarchy, same venture)	CPO 3 (whole hierarchy, any venture)
Pre-Submission Costs			
Out-of-pocket	1	2	3
Delay	1	2	3
Post-submission costs			
Potential out-of-pocket	3	2	1
Potential delay	3	2	1
Potential trade secret disclosure	1	2	3
Potential restrictions	1	2	3
Coverage	1	1	1

Note: For ordinal estimates, 0 = no cost, 1 = lowest cost, 2 and 3 = next lowest costs, respectively.

Coverage

There are no coverage differences attributable to the possession or control options.

INTER-RELATIONSHIPS AMONG ISSUES

The differences between comprehensive program options were addressed above by issue. There are, however, potential impacts which cannot be attributed to a single issue or to an alternative within that issue. For example, mandatory customer contact by itself may not pose much of a threat of trade secret disclosure. Yet, mandatory customer contact in combination with a disclosure policy in which trade secrets are not adequately protected could pose a significant threat to submitters and their customers. In essence, this relationship is an example of a possible synergistic impact. Other types of relationships between issues may not be synergistic, but may still involve dependencies. For example, the cost of supplemental reporting depends on the amount of the information requested and the probable extent of investigation by submitters to obtain that information.

The purpose of this chapter is to point out the nature of these inter-relationships, so they can be taken into account when comparing comprehensive program options. For purposes of analysis, the issues which make up a comprehensive program option are grouped as follows:

SCOPE OF REPORTING REQUIREMENTS	PROCEDURES	COVERAGE
• Notice Requirements	• Confidentiality	• Importer Provisions
• Possession or Control	• Insufficient Submissions	• Exporter Provisions
• Supplemental Reporting		• Customer Contact[12]
• Customer Contact		• Processor Reporting

The four issues included under scope of reporting requirements provide EPA with access to all the information theoretically available that is relevant to a section 5 decision for any particular chemical. Confidentiality and insufficient submissions are procedural issues because they do not define the reporting burden placed on submitters. Rather, they define procedures which help ensure that submitters comply with the reporting requirements. The specification of insufficient submission provisions are independent of the other issues and, therefore, are not discussed in this section. Coverage issues apply only to specific subgroups of affected parties; their differential impacts over comprehensive program options are defined primarily by the choice of reporting requirements and procedural policies.

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[12] Customer contact is a hybrid issue in the sense that the burden it imposes on submitters is related to depth and breadth of reporting requirements, but the burden it imposes on customers is primarily a coverage issue.

SCOPE OF REPORTING REQUIREMENTS

In theory, the combination of notice requirements, possession or control, supplemental reporting, and customer contact provide EPA with the authority to obtain all the available information that is relevant to a section 5 decision. It is possible to devise a rational vertical ranking in terms of the concern of submitters about these issues, regardless of the comprehensive program option being addressed. In order of decreasing concern to submitters, this ranking is as follows:

- notice requirements,
- possession or control,
- supplemental reporting, and
- customer contact.

The logic for this ranking is discussed below. First, the low rank of customer contact is explained, and then the other issues are addressed in pairs.

Customer contact, as defined in CPO 1 and CPO 2, will have little impact on submitters and is placed below supplemental reporting as an issue of concern, assuming only these two CPOs are being considered. The potential impact of customer contact on submitters is significantly greater under CPO 3, given the mandatory contact requirements for a very broad definition of customers. Therefore, under CPO 3, customer contact could be assumed to be of relatively greater importance to submitters.

The rationale for the relative importance of notice requirements, possession or control, and supplemental reporting is developed through comparison by pairs as follows:

- Notice Requirements/Supplemental Reporting;
- Possession or Control/Supplemental Reporting; and
- Notice Requirements/Possession or Control.

This section will be followed by a summary of the relative importance of each to submitters.

Notice Requirements/Supplemental Reporting

The more narrowly notice requirements are defined, the more likely supplemental reporting will be used. In the case where notice requirements are relatively comprehensive (i.e., the January 10, 1979 proposal), submitters may provide EPA with more information than is needed to make decisions, thereby incurring unnecessary costs; but supplemental reporting costs would then be minimal. In general, it would be less costly for submitters to meet less detailed notification requirements and risk additional supplemental reporting costs. In this way, submitters provide EPA with exactly the information needed to make section 5 decisions, and no more. Limiting the amount of information reduces the risk of trade secret disclosure and also insures that attention is paid to the correct information in the section 5 decision-making process. Thus, in terms of relative costs, notice requirements dominate supplemental reporting requirements as an issue of concern to submitters.

Possession or Control/Supplemental Reporting

A similar argument can be developed regarding the relationship of possession or control to supplemental reporting. As with notice requirements, submitters would prefer to minimize the initial burden so that any unnecessary costs can be avoided. Therefore, submitters would choose a narrow definition of "possession or control" and run the risk of additional supplemental reporting costs, no matter how the supplemental reporting rules are ultimately defined.

Notice Requirements/Possession or Control

The relationship between notice requirements and possession or control is a synergistic one. Thus, slight changes in both directons can have significant impacts on the joint effects. The relative importance of these two issues depends on individual data items. For example, given the choice, a submitter might choose to eliminate particularly sensitive requirements from the notice in exchange for a broader definition of possession or control for the remaining elements. Because notice requirements are the primary determinant of the reporting burden faced by submitters, notice requirements dominate possession or control.

CONFIDENTIALITY AND THE OTHER ISSUES

Confidentiality concerns are paramount. The relationship between confidentiality and reporting requirements is addressed in the next section. The following two sections will address the synergisms of confidentiality/ customer contact, and confidentialty/ importer provisions, respectively.

Confidentiality and Reporting Requirements

To submitters, the essential confidentiality issue is the degree to which trade secrets will be protected. In essence, the primary confidentiality concern can be cast in terms of the risk of disclosure. Notice requirements provide submitters with a risk of trade secret disclosure which could be measured as the product of two factors:

- quantity (and sensitivity) of trade secret data submitted, and

- probability of trade secret disclosure.

Presumably, the first factor is directly proportional to the scope of reporting requirements, and the second factor represents the result of any given confidentiality policy. Given the multiplicative nature of the relationship between these two factors, simultaneous small increases in both components could imply a significant increase in the burden to submitters. The multiplicative relationship between notice requirements, possession or control, and confidentiality policy creates the possibility that a comprehensive program option which is only slightly broader on all three of these issues may be significantly more burdensome to submitters.

Consider how the three comprehensive program options differ on reporting requirements and confidentiality policy:

	CPO 1	CPO 2	CPO 3
Reporting Requirements			
Notice	minimum guidance	reproposal	proposal
Possession or control	downward, same venture	whole hierarchy, same venture	whole hierarchy, no venture limits
Confidentiality			
Generic Policy	none	chem. ID, manuf. ID., use, phys. and chemical properties	chem. ID. manuf. ID., use, phys. and chemical properties
When to substantiate	5(d)(2) with notice	all with notice	all with notice

The reporting requirements increase from CPO 1 to CPO 3 according to both relevant dimensions. The major provisions of the confidentiality policy carry an increased burden in progressing from CPO 1 to CPO 2, but not from CPO 2 to CPO 3 (the differences between CPO 2 and CPO 3 relate to the substantiation questions and the issue of when and how to disclose chemical identity as part of a health and safety study). Although the generic requirements carry some additional risk of trade secret disclosure, it is reasonable to assume that this risk is independent of the scope of reporting requirements. (The responses to the four items for which generic information is required probably do not change significantly as reporting requirements grow.) However, the risk associated with substantiating all information at the time of submission increases with the scope of notice requirements. Thus, even though the differences between CPO 1 and CPO 2 do not appear great on an issue-by-issue basis, the combined effects of the differences in individual issues may be significant.

Confidentiality/Customer Contact

Although requirements for mandatory customer contact may not by themselves pose risks of trade secret disclosure, mandatory customer contact (especially with a broad definition of customers), in conjunction with a confidentiality policy where trade secrets may not be protected adequately, could pose a substantial threat to submitters and their customers. Submitters could be concerned that their customers might be able to piece together enough information about the new chemical to manufacturing it themselves.[13] Such subsequent manufacture by customers would not be subject to any section 5 requirements because the original manufacturer would have already submitted the notice. Similarly, submitters might be able to gather enough information from their customers' submission to consider downstream integration.

Only CPO 3 appears to present this type of joint risk from confidentiality/customer contact. However, this additional risk should be considered as an incremental cost of moving from CPO 2 to CPO 3.

Confidentiality/Importer Provisions

The problem here is that the importer defined for the purposes of section 5 may not be able to protect the trade secrets of foreign suppliers or manufacturers. Substantiation requirements under all three comprehensive program options require submitters to demonstrate that their competitive position will be harmed by disclosing the information asserted as confidential. Depending upon how an importer under section 5 is ultimately defined, it is possible that the importer will have access to sensitive information. The disclosure of such information may not harm the importer but could harm the foreign supplier or manufacturer. In this situation, the importer may not be able to assert that this information is confidential. In some cases, it may even be to the importers' advantage to have foreign manufacturers' confidential business information released (e.g., chemical identity and use) in the hope that a potentially cheaper source of the chemical becomes available.[14] The impact of this joint effect for CPOs 1 and 2 will depend on the specification of Alternative 2 for definition of importer (most knowledgeable person as defined by EPA). For CPO 3, the mechanics of implementing the combined responsibility approach to the definition of an importer are not sufficiently clear to allow for an assessment of the joint effects of confidentiality/importer provisions.

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[13] Comments of the Manufacturing Chemists Association on EPA Proposed Regulations for Premanufactures Notification Under Section 5 of TSCA, March 26, 1979, pp. 212-220.

[14] Comments of the American Importers Association, OTS-05002E, November 30, 1979, p. 13.

COMPARISON OF COMPREHENSIVE PROGRAM OPTIONS

In this section, the comprehensive program options are compared. Although it is not possible yet to describe the costs of any comprehensive program option completely in dollar terms, it is useful to organize the comprehensive program options by the groupings suggested in Chapter 2. This facilitates the comparison of comprehensive program options both horizontally and vertically and provides a rough framework for understanding the relative differences among them.

Domestic Manufacturers Producing For A Domestic Market

Exhibit 5-11 summarizes the issue-by-issue costs to domestic manufacturers producing for a domestic market, ranked by the hierarchy discussed earlier. The costs presented in Exhibit 5-11 are identical to those developed previously, and they have not been adjusted for interdependencies. Costs which are in dollars (pre-submission out-of-pocket notice and confidentiality costs) must be thought of in conjunction with costs attributable to other issues, as the footnotes to Exhibit 5-11 indicate. Although the direction in which these issues affect costs is known, the magnitude of the cost effects is not. Presubmission out-of-pocket notice costs need to consider possession or control. Presubmission out-of-pocket confidentiality costs need to consider notice requirements and possession or control. The rationale behind these two additional considerations is provided below.

The pre-submission out-of-pocket notice costs were derived from estimates prepared by ADL.[15] These estimates were developed under ADL's assumed "view of the likely response of a prudent firm." This probably would correspond to the definition of possession or control assumed in CPO 1 or CPO 2. Because CPO 1 and CPO 2 are both limited to companies participating in the same venture with the submitter, there is probably not much difference between the two, provided that CPO 2 does not extend the reach of CPO 1 to foreign firms. It is assumed that international considerations will significantly complicate possession or control because some countries have laws limiting the international flow of scientific and technical information. This problem might occur in a case where the submitter is a domestic subsidiary participating in the same venture with a foreign subsidiary of the same parent.

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[15] The costs for CPO 3 were derived from Impact of TSCA Proposed Premanufacturing Notification Requirements, December 1978; the costs for CPO 2 were estimated from Estimated Costs for Preparation and Submission of Reproposal Premanufacture Form, September 1979; the costs for CPO 1 were derived by ICF using the ADL methodology.

EXHIBIT 5-11

SUMMARY OF COSTS FOR DOMESTIC MANUFACTURERS PRODUCING FOR A DOMESTIC MARKET

Cost	Coverage	Pre-Submission		Post-Submission			
		Out-of-Pocket	Delay	Out-of-Pocket	Delay	Trade Secret Disclosure	Restrictions
Reporting Requirement							
CPO 1	Same	$1,000 to 7,500	1	3	3	1	1
CPO 2	Same	$1,200 to 8,900	2	2	2	2	2
CPO 3	Same	$3,700 to 42,000[a]	3	1	1	3	3
Possession or Control							
CPO 1		1	1	3	3	1	1
CPO 2		2	2	2	2	2	2
CPO 3		3	3	1	1	3	3
Supplemental Reporting							
CPO 1		0	0	1	2	1	1
CPO 2		0	0	2	1	2	2
CPO 3		0	0	3	1	3	3
Customer Contact							
CPO 1	No Customer Contact	0	0	0	0	0	0
CPO 2	No Mandatory Contact	1	0	1	1	0	1
CPO 3	Mandatory Contact	2	1	0	2	1	2
Confidentiality							
How and When to Assert and Substantiate		less than					
CPO 1		$900 to 6,400[b]	1	2	0	1	0
CPO 2		$900 to 6,400	2	1	0	2	0
CPO 3		$900 to 6,400[c]	2	1	0	2	0
Generic							
CPO 1		0	0	0	0	0	0
CPO 2		1	1	1	0	1	0
CPO 3		1	1	1	0	1	0
When to Disclose Chemical ID							
CPO 1		0	0	0	0	1	0
CPO 2		0	0	0	0	1	0
CPO 3		0	0	0	0	2	0
How to Disclose Chemical ID							
CPO 1		0	0	0	0	1	0
CPO 2		0	0	0	0	2	0
CPO 3		0	0	0	0	2	0
Insufficient Submissions							
CPO 1		0	0	1	1	1	1
CPO 2		0	0	1	2	1	1
CPO 3		0	0	1	1	1	1

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[a] Range specified is likely an underestimate due to the reach of possession or control under CPO 3.

[b] Range specified is likely an underestimate due to notice requirements and possession or control under CPO 1.

[c] Range specified is likely an underestimate due to notice requirements and possession or control under CPO 3.

Note: For ordinal estimates, 0 = no cost, 1 = lowest cost, 2 = next lowest cost, etc. Ordinal estimates are meaningful only within issues.

Under CPO 1, the submitter would not be in possession or control of the foreign firm's data, whereas under CPO 2 the submitter would be. Thus, CPO 2 could extend the reach of possession or control to foreign firms in limited situations. However, the definition of possession or control under CPO 3 has a much broader reach, because it is not limited to the current venture. Therefore, in any case where the submitter is part of an overall corporate hierarchy which includes foreign subsidiaries, problems of international information transfer will occur. Thus, out-of-pocket pre-submission notice costs for CPO 3 should be adjusted to account for this difference.

Presubmission out-of-pocket costs for confidentiality need to be similarly adjusted. The estimates which appear in Exhibit 5-11 are derived from ADL's out-of-pocket estimates for the reproposed confidentiality policy. Although the cost ranges are specified for "a generalized method of asserting and substantiating claims of confidentiality," it seems reasonable to assume that these ranges were based on a notice form and a definition of possession or control approximated by the reproposal. Therefore, the pre-submission out-of-pocket confidentiality costs for CPO 3 would be significantly higher, and the pre-submission out-of-pocket confidentiality costs for CPO 1 would be slightly lower, as the footnotes indicate. In making these assessments, one should remember that the relationship between notice requirements, possession or control, and confidentiality is multiplicative rather than additive.

Importers

Exhibit 5-12 contains a summary of costs for importers. Coverage differences and pre-submission out-of-pocket cost differences are the major differences between Exhibit 5-11 and 5-12. Adjustments to pre-submission out-of-pocket costs for both reporting requirements and confidentiality need to be considered, as discussed previously and as the footnotes in Exhibit 5-12 indicate. Confidentiality costs are complicated further by the potential problem of an importer who is unable to substantiate the trade secrets of a foreign supplier/manufacturer. The inability to substantiate the claims could either increase or decrease out-of-pocket confidentiality costs to importers, depending upon whether or not EPA develops a mechanism for foreign manufacturers to protect their trade secrets.

Foreign Manufacturers/Suppliers

Exhibit 5-13 summarizes the costs to foreign manufacturers/suppliers under each of the comprehensive program options. Because the foreign manufacturer/supplier submission is essentially a supplement to an importer section 5 submission, the issues of possession or control, supplemental reporting, customer contact, and insufficient submissions are assumed not to affect the foreign manufacturer/supplier submission. Foreign manufacturers/suppliers are assumed to make an effort in good faith to respond.

EXHIBIT 5-12

SUMMARY OF COSTS FOR IMPORTERS

Cost	Coverage	Pre-Submission		Post-Submission			
		Out-of-Pocket	Delay	Out-of-Pocket	Delay	Trade Secret Disclosure	Restrictions
Reporting Requirement							
CPO 1	Principal	$ 800 to 7,500	1	3	3	1	1
CPO 2	Combined Resp.	$ 900 to 8,900	2	2	2	2	2
CPO 3	Combined Resp.	$2,300 to 26,700[a]	3	1	1	3	3
Possession or Control							
CPO 1		1	1	3	3	1	1
CPO 2		2	2	2	2	2	2
CPO 3		3	3	1	1	3	3
Supplemental Reporting							
CPO 1		0	0	1	2	1	1
CPO 2		0	0	2	1	2	2
CPO 3		0	0	3	1	3	3
Customer Contact							
CPO 1	No Customer Contact	0	0	0	0	0	0
CPO 2	No Mandatory Contact	1	0	1	1	0	1
CPO 3	Mandatory Contact	2	1	0	2	1	2
Confidentiality							
How and When to Assert and Substantiate[d]		less than					
CPO 1		$900 to 6,400[b]	1	2	0	1	0
CPO 2		$900 to 6,400	2	1	0	2	0
CPO 3		$900 to 6,400[c]	2	1	0	2	0
Generic							
CPO 1		0	0	0	0	0	0
CPO 2		1	1	1	0	1	0
CPO 3		1	1	1	0	1	0
When to Disclose Chemical ID							
CPO 1		0	0	0	0	1	0
CPO 2		0	0	0	0	1	0
CPO 3		0	0	0	0	2	0
How to Disclose Chemical ID							
CPO 1		0	0	0	0	1	0
CPO 2		0	0	0	0	2	0
CPO 3		0	0	0	0	2	0
Insufficient Submission							
CPO 1		0	0	1	1	1	1
CPO 2		0	0	1	2	1	1
CPO 3		0	0	1	1	1	1

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[a] Range specified is likely an underestimate due to reach of possession or control under CPO 3.

[b] Range specified is likely an underestimate due to notice requirements and possession or control under CPO 1. Also, the phenomenon of importers not necessarily being able to substantiate the trade secrets of foreign suppliers complicates this cost assessment.

[c] Range specified is likely a significant underestimate due to notice requirements and possession or control under CPO 3. There are additional complications due to considerations as mentioned above.

[d] The cost ranges specified here are based on confidentiality costs for the domestic manufacturer's form, even though the importer's form is less broad than the domestic manufacturer's form.

Note: For ordinal estimates, 0 = no cost, 1 = lowest cost, 2 = next lowest cost, etc. Ordinal estimates are meaningful only within issues.

EXHIBIT 5-13

SUMMARY OF COSTS FOR FOREIGN MANUFACTURERS/SUPPLIERS

Cost	Coverage	Pre-Submission		Post-Submission			
		Out-of-Pocket	Delay	Out-of-Pocket	Delay	Trade Secret Disclosure	Restrictions
Reporting Requirement							
CPO 1	Same	$ 300 to 1,500	1	3	3	1	1
CPO 2	Same	$1,800 to 7,200	2	2	2	2	2
CPO 3	Same	$3,000 to 11,600[a]	3	1	1	3	3
Possession or Control							
CPO 1		0	0	0	0	0	0
CPO 2		0	0	0	0	0	0
CPO 3		0	0	0	0	0	0
Supplemental Reporting							
CPO 1		0	0	0	0	0	0
CPO 2		0	0	0	0	0	0
CPO 3		0	0	0	0	0	0
Customer Contact							
CPO 1	No Customer Contact	0	0	0	0	0	0
CPO 2	No Mandatory Contact	0	0	0	0	0	0
CPO 3	Mandatory Contact	0	0	0	0	0	0
Confidentiality							
How and When to Assert and Substantiate[b]		less than					
CPO 1		$900 to 6,400	1	2	0	1	0
CPO 2		$900 to 6,400	2	1	0	2	0
CPO 3		$900 to 6,400	2	1	0	2	0
Generic							
CPO 1		0	0	0	0	0	0
CPO 2		1	1	1	0	1	0
CPO 3		1	1	1	0	1	0
When to Disclose Chemical ID							
CPO 1		0	0	0	0	1	0
CPO 2		0	0	0	0	1	0
CPO 3		0	0	0	0	2	0
How to Disclose Chemical ID							
CPO 1		0	0	0	0	1	0
CPO 2		0	0	0	0	2	0
CPO 3		0	0	0	0	2	0
Insufficient Submission							
CPO 1		0	0	0	0	0	0
CPO 2		0	0	0	0	0	0
CPO 3		0	0	0	0	0	0

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[a] Range specified is likely an underestimate due to reach of possession or control under CPO 3.

[b] Range specified is likely an underestimate due to reduced scope of the foreign manufacturers/suppliers form.

Note: For ordinal estimates, 0 = no cost, 1 = lowest cost, 2 = next lowest cost, etc. Ordinal estimates are meaningful only within issues.

Foreign manufacturers/suppliers have special confidentiality concerns. It may be that importers will possess information that is sensitive to foreign manufacturers/suppliers which they will not be able to protect. Thus, unless EPA institutes a mechanism to ensure that foreign manufacturers have an opportunity to assert and substantiate information in the importer's submission, foreign manufacturers/suppliers may bear a special risk of trade secret disclosure.

Exporters

Exhibit 5-14 summarizes the costs of the three comprehensive program options to domestic manufacturers who produce new chemicals solely for export. Under CPO 1, these manufacturers must submit a section 8(a) notice before manufacturing solely for export. Because these manufacturers are exempt from section 5 reporting, no costs of this option are technically attributable to section 5. In Exhibit 5-14, no costs are shown for CPO 1 (other than pre-submission costs for reporting requirements, which are provided for comparative purposes) because CPO 1 is not a section 5 rule. However, it is still possible for submitters to incur other costs, but such costs would be attributable to other parts of the statute.

Differences between CPO 2 and CPO 3 parallel the explanations developed previously. Presubmission out-of-pocket costs for reporting requirements need to be adjusted upward for the deeper reach of possession or control under CPO 3. Presubmission out-of-pocket costs for confidentiality under CPO 3 need to be adjusted upward for the broader reporting requirements and deeper possession or control definition applicable to CPO 3. However, this increased cost would be offset somewhat by the fact that reporting requirements for domestic manufacturers that produce for domestic consumption (on which the confidentiality out-of-pocket costs were based) are greater than reporting requirements for exporters.

Processors

Exhibit 5-15 summarizes the costs for processors. CPO 1 requires processors to file a section 8(a) notice equivalent to the reproposed form of October 1979. CPO 2 requires processors to file a section 5 notice as proposed on August 15, 1980. CPO 3 requires only processors who are also the manufacturer or importer to file a section 5 notice equivalent to the proposed form of January 1979 (i.e. the separate processor does not file a notice). The logic for the cost estimates parallels the logic for domestic manufacturers producing for a domestic market.

EXHIBIT 5-14

SUMMARY OF COSTS FOR EXPORTERS

Cost	Coverage	Pre-Submission		Post-Submission			
		Out-of-Pocket	Delay	Out-of-Pocket	Delay	Trade Secret Disclosure	Restrictions
Reporting Requirement							
CPO 1	Small Bus. Exemp.	$1,200 to 8,100	0[a]	0	0	0	0
CPO 2	No Exemptions	$1,200 to 8,100	1	2	2	1	1
CPO 3	No Exemptions	$2,500 to 40,300[b]	2	1	1	2	2
Possession or Control							
CPO 1		0	0	0	0	0	0
CPO 2		1	1	2	2	1	1
CPO 3		2	2	1	1	2	2
Supplemental Reporting							
CPO 1		0	0	0	0	0	0
CPO 2		0	0	1	1	1	2
CPO 3		0	0	2	1	2	1
Customer Contact							
CPO 1	No Customer Contact	0	0	0	0	0	0
CPO 2	No Mandatory Contact	1	0	1	1	0	1
CPO 3	Mandatory Contact	2	1	0	2	1	2
Confidentiality							
How and When to Assert and Substantiate[c]							
CPO 1		none	0	0	0	0	0
CPO 2		$900 to 6,400	1	1	0	1	0
CPO 3		$900 to 6,400[d]	1	1	0	1	0
Generic							
CPO 1		0	0	0	0	0	0
CPO 2		1	1	1	0	1	0
CPO 3		1	1	1	0	1	0
When to Disclose Chemical ID							
CPO 1		0	0	0	0	0	0
CPO 2		0	0	0	0	1	0
CPO 3		0	0	0	0	2	0
How to Disclose Chemical ID							
CPO 1		0	0	0	0	0	0
CPO 2		0	0	0	0	1	0
CPO 3		0	0	0	0	1	0
Insufficient Submission							
CPO 1		0	0	0	0	0	0
CPO 2		0	0	1	2	1	1
CPO 3		0	0	1	1	1	1

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[a] Although this cost is a cost, it is not a Section 5 cost. Therefore, a rule based on section 8 authority has no sector 5-related cost.

[b] Range specified is likely an underestimate due to reach of possession or control under CPO 3.

[c] Range specified is likely an underestimate due to the fact that the exporter's form is narrower than the domestic manufacturer's form.

[d] Range specified is likely an underestimate due to notice requirements and possession or control under CPO 3.

Note: For ordinal estimates, 0 = no cost, 1 = lowest cost, 2 = next lowest cost, etc. Ordinal estimates are meaningful only within issues.

EXHIBIT 5-15

SUMMARY OF COSTS FOR PROCESSORS

Cost	Coverage	Pre-Submission		Post-Submission			
		Out-of-Pocket	Delay	Out-of-Pocket	Delay	Trade Secret Disclosure	Restrictions
Reporting Requirement							
CPO 1	all	$724 to 4,450	1	0	0	1	0
CPO 2	all	$1,200 to 8,900	1	2	2	1	1
CPO 3	only manufacturer or importer	$3,700 to 42,000[a]	2	1	1	2	2
Possession or Control							
CPO 1		0	0	0	0	0	0
CPO 2		1	1	2	2	1	1
CPO 3		2	2	1	1	2	2
Supplemental Reporting							
CPO 1		0	0	0	0	0	0
CPO 2		0	0	1	1	1	1
CPO 3		0	0	2	1	2	2
Customer Contact							
CPO 1	No Customer Contact	0	0	0	0	0	0
CPO 2	No Mandatory Contact	1	0	1	1	0	1
CPO 3	Mandatory Contact	2	1	0	2	1	2
Confidentiality							
How and When to Assert and Substantiate							
CPO 1		None	0	0	0	0	0
CPO 2		$900 to 6,400	1	1	0	1	0
CPO 3		$900 to 6,400[b]	1	1	0	1	0
Generic							
CPO 1		0	0	0	0	0	0
CPO 2		1	1	1	0	1	0
CPO 3		1	1	1	0	1	0
When to Disclose Chemical ID							
CPO 1		0	0	0	0	0	0
CPO 2		0	0	0	0	1	0
CPO 3		0	0	0	0	2	0
How to Disclose Chemical ID							
CPO 1		0	0	0	0	0	0
CPO 2		0	0	0	0	1	0
CPO 3		0	0	0	0	1	0
Insufficient Submissions							
CPO 1		0	0	0	0	0	0
CPO 2		0	0	1	2	1	1
CPO 3		0	0	1	1	1	1

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[a] Range specified is likely an underestimate due to reach of possession or control under CPO 3.

[b] Range specified is likely an underestimate due to notice requirements and possession or control under CPO 3.

Note: For ordinal estimates, 0 = no cost, 1 = lowest cost, 2 = next lowest cost, etc. Ordinal estimates are meaningful only within issues.

CHAPTER 6

IDENTIFYING INNOVATIVE CHEMICAL INDUSTRY SEGMENTS

In previous chapters three factors critical to the economic impact analysis were presented. In Chapter 2 a segmentation scheme for the industry based on chemical properties was presented. The broad segments were inorganics, high polymers, amphipathic compounds, elementary organic chemicals, organic chemicals, NEC, catalysts, and other chemical products. In Chapter 4 the kinds of impacts that section 5 notice provisions may impose were identified. These impacts were direct out-of-pocket costs, delays, and various costs tied to uncertainty. In Chapter 5 the regulatory issues were analyzed to determine how the costs differed among options and monetary costs were assigned whenever possible. The next step in analyzing the impact of these costs on the chemical industry is to define the affected groups.

Specifying the groups most affected is difficult because all chemical segments are engaged in broadly defined innovative activity. Although some innovations may be new products, equally rewarding process innovations can be placed into the production process. By limiting the analysis to those segments that introduce many new chemical entities, we can better focus the impact analysis.

This chapter presents a summary description of the industry segments and an identification of the sub-segments which are potential sources of substantial new chemical entity innovation. The chapter concludes with a review of the most innovative segments.

The segments are discussed in this order: inorganic chemicals, synthetic high polymers, amphipathic compounds, elementary organic chemicals, organic chemicals, NEC, catalysts, and other chemical products. Appendix E contains the comprehensive profiles of segments and sub-segments briefly discussed here. In addition, ADL's report published in December 1978 includes information about various chemical industry segments.

INORGANIC CHEMICALS

Inorganic chemicals are chemicals that are not carbon-based. Their relatively limited ability to bond restricts their capacity to form larger molecules and, as a result, reduces their structural and functional diversity.

Lowered bonding ability also accounts for the comparatively minor product innovation in the area of inorganic chemicals. The fact that the study of inorganic chemicals is one of the oldest fields in chemistry also explains, in part, why innovation is slow and infrequent in this segment of the industry.

- Many important products have the status of commodity chemicals--standardized products produced on a very large scale.
- Commodity chemicals tend to be produced by large companies, and the markets are often highly concentrated. Because of the importance of commodity chemicals in the inorganic chemicals segment, market concentration is higher in inorganics than in other segments of the chemical industry.
- There is a great premium on process innovation in the commodity chemicals and in the inorganic chemicals in general. Even though producers find it difficult to capture new markets by introducing new products, manufacturers may be able to lower costs, lower prices, and capture new markets or additional market shares by improving the efficiency of their production processes.
- There is a concentration of research and development expenditures in engineering process innovation rather than in basic scientific research.

Despite the limited innovation in the inorganic chemicals segment, this section of the industry has developed some new boron, phosphate, and silicon compounds in recent years. Some firms have been working with rare earth salts, but they have yet to produce these salts in sufficient quantities for commercial development. In addition, process innovation often leads to the development of new chemical intermediates.

The direction of future innovation in inorganic chemicals may not resemble historical trends. In recent years an increased theoretical understanding of inorganic chemistry has emerged from research laboratories. To date, these theoretical breakthroughs have not lead to the development of new products. But there may be some commercialization in the future which would contribute substantially to further innovation.

Some of the most important producers of inorganic chemicals are Diamond Shamrock, FMC, Freeport Minerals, Kerr-McGee, NL Industries, Occidental Petroleum (through its Hooker Chemical subsidiary), Olin, PPG, and Stauffer Chemical. Union Carbide, Airco, and Air Products & Chemicals are the three leading producers of industrial gases, and DuPont, NL Industries, and Glidden are the three leading producers of inorganic pigments. Major fertilizer producers include The Williams Companies, Farmland Industries, CF Industries, American Cyanamid, W.R. Grace, Occidental Petroleum (Hooker Chemical), and U.S. Steel.

SYNTHETIC HIGH POLYMERS

Synthetic high polymers are chain-like macromolecules formed by the chemical linkage of smaller molecular units known as monomers. Depending upon the nature of the monomers, these compounds can assume the form of plastics, resins, fibers, or rubbers and are used in the fabrication of a wide variety of industrial and consumer goods.

The basic polymer types currently in use date largely from the period 1930 through 1960. Some important new polymer types have been developed since then--polysulfone plastic by Union Carbide (1965), olefin fibers by Hercules (1962), and Anidex fibers by Rohm & Haas (1969)--but the synthetic high polymers industry is built upon polymer types that were first developed a generation ago. A relatively small number of these basic polymer types have large market shares. For example, in 1978 polyester accounted for almost half of domestic non-cellulosic organic fiber production and nylon accounted for almost one-third. Forty to 50 basic plastics are available commercially, but in 1976 polyethylene accounted for 29 percent of domestic production; polyvinyl chloride, for 15 percent; and polypropylene, for almost nine percent. In 1976 styrene-butadiene rubber constituted more than half of all U.S. synthetic rubber output.[16]

These characteristics of synthetic high polymers--a small number of basic products that are made in very large volumes which have dominated the industry for years--lead to a market structure which is dominated by large plants owned by large companies. Concentration in synthetic high polymer markets is relatively high and especially apparent in the synthetic fibers market. In 1976 DuPont alone controlled 35 percent of domestic synthetic fiber production, and the top four firms (DuPont, Celanese, Monsanto, Eastman Kodak) controlled two-thirds of domestic production. The top four synthetic rubber producers (Goodyear, Firestone, DuPont, Goodrich) accounted for half the domestic production in 1976, and the top eight for 72 percent. The plastics market displays the lowest degree of concentration: in 1976 the top four producers (DuPont, Dow, Monsanto, Union Carbide) accounted for 27 percent of domestic production, and the top eight firms for 38 percent.[17]

The leading plastics producers are large, diversified chemical firms whose production of plastics represents only a small part of total production. The plastics sales of only two, of the top twenty firms in 1976, exceeded 16 percent of the total chemical sales of the company.[18] Sales of plastics represented less than 10 percent of total chemical sales of most plastics-producing companies. Man-made fiber production represents a much greater percentage of total corporate chemical sales among man-made fiber producers. Man-made fiber sales as a percentage of total chemical sales exceeded 10 percent for all of the top ten man-made fiber producers, and for five of them these sales were more than one-third of total chemical sales.[19] Most of the leading synthetic rubber producers are tire and oil companies for whom synthetic rubber represents only a small proportion of total sales.

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[16] Mary K. Meegan, ed., Kline Guide to the Chemical Industry (3rd ed., Charles Kline & Co., 1977).

[17] Ibid.

[18] Ibid.

Because of the characteristics of synthetic high polymer markets discussed above, the chances are slight that a new, radically different generic fiber able to compete successfully with the current major fibers could be developed and produced. First of all, finding such a fiber in this well-researched field would be difficult. Then, building large-capacity plants and establishing the product in the man-made fiber market would require major expenditures.

The last generic fiber introduced was Anidex by Rohm & Haas in 1969. Rohm & Haas reputedly spent $20 million and 10 years in research. A 1977 estimate by an industry executive set expenditures of time and money respectively at $50 million and five to ten years of development to commercialize a new generic product for broad-based market application.[20]

Although the roster of basic polymers is quite steady, the synthetic high polymer industry sends out a steady stream of new polymers that eventually bring new products into being. Recently, there has been intense innovation in copolymers. Copolymers and polymers differ only by virtue of the number of types of monomers in their composition: copolymers use two or more; polymers use a single type. Both use the same components but in different constructs.

Producing copolymers is only one way to introduce new products to the market. For example, manufacturers are able to produce literally thousands of different formulations, tailored to specific uses, by using additives to change color, flexibility, stability, tensile strength, electrical conductivity and other properties. Manufacturers can also create new products by varying the methods used to process the basic materials. For example, in 1977, Hercules, the largest producer of polypropylene, had more than 150 polypropylene products available.[21] Most of the additives which are used to produce these products are covered in another segment--Organic Chemicals, NEC.

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[19] Ibid.

[20] American Chemical Society, Chemistry in the Economy, 1973, a study supported in part by the National Science Foundation.

[21] "Polypropylene: R&D is the Key," Chemical Marketing Reporter, March 14, 1977.

AMPHIPATHIC COMPOUNDS

All amphipathic compounds consist of two parts. The hydrophilic part, or hydrophile, is soluble in water. The hydrophobic (lipophilic) part is soluble in oil. Usually these molecules are large enough for each part to display its own solubility behavior. The parts that are not soluble in the particular chemical environment surrounding them are chemically attracted to each other. As a result, the molecules huddle together with the insoluble parts forming their own environment inside the huddle. These huddles, called micelles, are of microscopic size and are spherically shaped. Particles not soluble in the solution may be dissolved in these micelles. This is what accounts for the relatively high dissolving capabilities of many amphipathic compounds such as detergents.

Amphipathic compounds comprise an interconnected group of products with diverse industrial structures and levels of innovation. They consist of soaps, synthetic detergents, surfactants, and fatty acids. Soaps, glycerin, and fatty acids are primarily natural products and are not innovative in the sense used in this report. The synthetic detergent industry is highly innovative, but much of this is process innovation or the development of new formulations of the same chemical substances. The bulk of the innovation in synthetic detergents comes from the development of new surfactants.

Surfactants (short for surface active agents) are organic compounds that reduce surface tension. They wet surfaces easily, remove and suspend dirt, disperse particles, emulsify oil and grease, and produce foam. The first synthetic surfactants were developed during World War I by the Germans because of a shortage of natural fats from which natural surfactants (soaps) are derived. New types of synthetic surfactants were developed during the period between the two world wars, but rapid growth in the use of synthetic surfactants did not come until the 1950s with the development of alkylbenzene sulfonate (ABS). In the 1960s concern over the accumulation of nonbiodegradable chemicals (such as ABS) in the environment led industry to spend several hundred million dollars to develop linear alkylbenzyl sulfonate (LAS).[22] LAS is not completely acceptable because it breaks down slowly and incompletely. As a result, LAS was banned in many areas, and research on new surfactants which are both environmentally acceptable and effective is underway.

The pressure to develop environmentally acceptable surfactants has produced a significant degree of innovation in the surfactant industry. The surfactant industry has also developed new surfactants for uses other than in synthetic detergents, such as food processing, oil processing, and emulsion polymerization. Overall, ICF believes, based on our analysis (see Appendix E), that the level of innovation in the surfactant industry is high.

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[22] American Chemical Society, Chemicals in the Economy, p. 200.

Approximately half the total surfactant production is captively consumed by detergent companies such as Proctor & Gamble, Lever Brothers, and Colgate-Palmolive. Diamond Shamrock, Stepan, ICI United States and a number of smaller firms sell surfactants to other firms.[23]

Synthetic detergents are mixtures of surfactants, builders, bleaching agents, corrosion inhibitors, and other agents that are used to clean surfaces such as textiles, cooking and eating utensils, walls and floors, and metals. They are also used for human cleaning. The growth of synthetic detergents has been tied to the increased use and development of surfactants.

The synthetic detergent industry has two separate markets: household and industrial. The domestic household detergent market is dominated by Proctor & Gamble (50 percent of the market) and by Colgate-Palmolive and Lever Brothers (each with 17 percent of the market). In contrast, the industrial market is highly diversified. Most firms are regional: fewer than 30 companies operate on a national basis, and only 14 have domestic sales of $25 million or more. These fourteen companies share 50 percent of the market, and the other 3000 firms in the industry share the remaining 50 percent.[24]

The synthetic detergent industry is highly innovative, but much of that innovation involves new formulations and better processes. The chemical innovation primarily involves surfactants which were discussed above.

Fatty acids, glycerins, and soaps are primarily natural products, and the industries which produce them are not very innovative. Fatty acids and glycerins are produced by a large number of firms, but soap production is highly concentrated.

ELEMENTARY ORGANIC CHEMICALS

Elementary organic chemicals are the simple alkanes, olefins and aromatics which are obtained directly from petroleum, coal, and wood. Although the products can be varied to some extent by making minor adjustments in the production processes, emphasis is always placed on the production of a relatively small number of basic compounds which serve as the building blocks for the entire organic chemical industry.

Before World War II, the basic chemical building blocks were derived primarily from coal tar, a by-product of coke manufacture. But, with the development of the Middle East oil fields after World War II, petroleum displaced coal as the primary chemical feedstock. Although the basic chemical building blocks could also be obtained from gum and wood chemicals, in practice they are not. The major types of gum and wood chemicals are turpentine, charcoal, rosin, and tall oil.

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[23] Meegan, Kline Guide, p. 166.

[24] Chemical Week, August 22, 1973.

Product innovation in this segment is virtually non-existent, but increases in petroleum prices during the last ten years have stirred renewed interest in coal-based chemical feedstocks. Such a switch would result in significant process innovation in the chemical industry and the development of new catalytic preparations. However, the intricate oil-based network, developed over the last 30 years, would undoubtedly act to slow any conversion from petroleum to coal. The increase in petroleum prices has also renewed interest in biomass-based chemicals, but again, any expansion will be slow.

The production of petroleum refinery products, by far the predominant activity in this segment, is relatively unconcentrated and has changed little over the years. In both 1958 and 1972, the top four firms accounted for 13 percent of the total value of shipments.[25] Petroleum products are produced by almost all major chemical and petroleum companies.

Cyclic crudes are organic chemicals which are isolated from coal tar. Almost all cyclic crudes have identical counterparts produced in petroleum refineries, and the petroleum-derived products dominate the market. Consequently, production of cyclic crudes is quite small: in 1977 production was $250 million compared to almost $3 billion for the petroleum-derived products. The market is also highly concentrated: in 1972 the top four firms produced more than 90 percent of the cyclic crudes.[26]

Gum and wood chemicals such as rosin, turpentine, tall oil, and charcoal are obtained from living and dead trees. Concentration in the entire industry is relatively high: in 1972 the four-firm concentration ratio was 49 percent, and the eight-firm concentration ratio was 64 percent. The production of soft wood distillation products is highly concentrated (a four-firm concentration ratio of 90 percent in 1972), but the production of other gum and wood chemicals, including gums, charcoal, and tall oil is much less concentrated (a four-firm concentration ratio of 36 percent in 1972).[27]

The most important producers of petroleum refinery products are the leading petroleum refiners--Exxon, Standard Oil of Indiana, Standard Oil of California, and Texaco. Major producers of gum and wood chemicals include Hercules, Monsanto, Reichhold, Union Camp, Westvaco, and Shelton Naval Stores.

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[25] U.S. Department of Commerce, Bureau of Census, "Concentration Ratios in Manufacturing Industry," 1972 Census of Manufacturers, (Washington, D.C.: Government Printing Office).

[26] Ibid.

[27] Ibid.

ORGANIC CHEMICALS, NOT ELSEWHERE CLASSIFIED

The organic chemicals, NEC segment consists of organic chemicals that do not fit into the other organic chemical categories because of their unique structures and functions. As a whole, this segment is highly innovative, although some of its components, such as synthetic organic dyes and pigments, and miscellaneous acyclic chemicals, are not.

Cyclic intermediates are distinguished from other chemicals by both structure and function. Cyclic intermediates all consist of various functional groups which are attached to, or built into, a carbon framework that contains at least one ring. Cyclic intermediates are typically used in the production of end-use products, although they themselves may also have end uses as biocides, photographic chemicals, fuel additives, and antioxidants.

There are a few cyclic intermediates which have always dominated the industry. A group of 11 (cumene, cyclohexane, ethylbenzene, styrene, o-xylene, p-xylene, alkyl benzene, aniline, chlorobenzene, phenol, and phthalic anhydride) has traditionally accounted for 65 to 70 percent of production volume and 40 to 50 percent of sales volume.[28/] But despite the dominance of these large-volume commodity chemicals, innovation in this component is quite high. In general, there are many paths by which end-use chemicals can be produced from the initial feedstock. Each process innovation, in which a new path from feedstock to end use product is discovered, may result in the production of several new chemical intermediates for use in the new process. In addition, new intermediates may result from the search for new end-use products.

It is difficult to discuss the structure of the cyclic intermediate industry in its entirety. The large-volume commodity chemicals typically have more than 10 major producers, yet many of the small-volume intermediates are produced by only one firm. Because there are many ways to produce most cyclic compounds, there is some competition among the different intermediates. It is also important to note that oil companies command a significant share of the market, particularly in the production of large volume commodity chemicals. They have been attracted to the industry by the close relationship of many cyclics to refinery products.

Miscellaneous cyclic chemicals include end-use cyclic compounds such as gas and oil additives, many oil field chemicals, photographic chemicals, tanning materials, paint driers, enzymes, and some flavorings. In general, there is a high rate of innovation among end-use cyclics, just as there is among intermediate cyclics. It is difficult to say much more about the innovative nature and structure of the industries producing miscellaneous end-use cyclics, because data on these chemicals are often grouped with miscellaneous acyclic chemicals, a much larger though non-innovative group.

[28/] U.S. International Trade Commission, Synthetic Organic Chemicals (Washington, D.C.: Government Printing Office).

Miscellaneous acyclic chemicals are frequently used as intermediates, but also find end uses as gasoline additives, refrigerants, preservatives, oilwell chemicals, foods, antifreeze, and biocides. Little else is known about this component, because its data are often combined with data on miscellaneous cyclics. However, the industry experts that ICF contacted stated that this segment is non-innovative.

Plasticizers are organic chemicals that are physically incorporated into plastics to make their manufacture easier or to make the final product more flexible. About 85 percent of all plasticizers are used in the plastics industry (about two thirds of the total in polyvinyl chloride alone). The rest are used in the production of rubber and cellulose products.[29]

Our analysis (see Appendix E) has led us to conclude that there is considerable innovation in the plasticizer industry, particularly in the relatively new polymeric plasticizers. Even though the roster of basic plastics has been relatively unchanged for 20 years, thousands of new end-use products have been developed during that time from these basic plastics. Often, a new product will be associated with a new type of plasticizer.

In the mid-1970s, the leading four firms (Monsanto, W.R. Grace, U.S. Steel, and Exxon) produced just over 50 percent of all plasticizers, and the leading eight firms (the firms previously named and FMC, Union Carbide, Eastman Kodak, and Stauffer) produced just over 70 percent.[30] In more narrowly defined markets (e.g., phthalates, phosphate esters, polymeric plasticizers), the concentration ratios are somewhat higher. There has been some turnover among the leading plasticizer producers in the last 20 years. Allied Chemicals and Celanese, both among the leading plasticizer producers in the 1960s, no longer produce plasticizers, and Union Carbide no longer produces phthalate plasticizers. U.S. Steel, Exxon, Stauffer, Tenneco, and BASF Wyandotte have become major plasticizer producers either by buying small producers and expanding or by beginning production from scratch.[31]

Rubber-processing chemicals include a wide variety of substances that are used to modify rubber so it can be used in commercial applications. Not all of the chemicals used in rubber production are included in this category. Products such as sulfuric acid, salt, alum, sulfur, zinc oxide, fatty acids, silicas, clays, carbon black, nylon, rayon and pigments have many uses outside the rubber industry and are not included in this segment. The major categories of rubber-processing chemicals are:

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[29] "Plasticizers," Modern Plastics, September 1975, p. 47.

[30] Meegan, Kline Guide.

[31] Meegan, Kline Guide and Chemical and Engineering News, November 13, 1961, pp. 134-135.

(1) Accelerators: cause rubber to vulcanize faster and often retard aging;

(2) Activators: increase the efficiency of vulcanization;

(3) Antioxidants: protect rubber from deterioration due to the action of oxygen and oxidizing chemicals; and

(4) Antiozonants: protect rubber from deterioration due to the action of ozone.

As with plastics, there has not been much innovation in the roster of basic synthetic rubbers during the last 20 years, but hundreds of new end-use products have been developed from those basic rubbers. One or more new rubber-processing chemicals are associated with many of these products. New rubber-processing chemicals have been introduced -- established types, as well as entirely new types.

The major tire companies are important producers of rubber-processing chemicals. Goodrich, Goodyear, and Uniroyal produce about half of the total. Much of the volume produced by major rubber producers is used in their own rubber factories. It should be noted that the advantage that a high degree of concentration would normally give the rubber-processing chemicals industry is somewhat negated by the high degree of concentration among rubber producers, the buyers of rubber-processing chemicals.

Synthetic organic dyes and pigments' production is highly concentrated. In 1976, the four largest producers of organic dyes (DuPont, CibaGeigy, Mobay, and Sandoz) accounted for 55 percent of U.S. sales in organic dyes, and the four largest producers of pigments (DuPont, Chemetron, American Cyanamid, and Sun Chemical) accounted for 48 percent of U.S. pigment sales.[32] This industry is quite mature and innovation is not high. EPA has received a large number of section 5 notice submissions for chemicals in this segment. However, ICF does not believe that generalizations regarding long-term trends can be made now based on this experience.

CATALYSTS

A catalyst is a substance which promotes a chemical reaction without being consumed by the reaction. After the reaction is over, the catalyst can usually be used once again to promote the same reaction. Many commodity chemicals with a wide range of applications are also used as catalysts. Sulfuric acid, phosphoric acid, hydrofluoric acid, and caustic soda are important examples of this type of catalyst. But catalysts are more commonly chemicals whose sole function is to promote reactions. Many contain metals such as cobalt, nickel, molybdenum, vanadium, platinum, aluminum, palladium, and copper. In 1978 about 35 percent of all catalysts (by value) were used

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[32] Kline Industrial Marketing Guide, (Charles Kline & Co.), p. 158.

Administration (OSHA). Formaldehyde emissions from the urea formaldehyde adhesives utilized in construction have also come under government scrutiny. Concern about the carcinogenity of materials and the high levels of energy needed to produce many existing adhesives have prompted a search for new products. And a number of new products have recently been introduced.

The adhesives and sealants industry is very unconcentrated. In 1977 there were 750 manufacturers, with the top 50 accounting for 68 percent of industry sales. The large companies usually have a wide product line; the smaller companies specialize in product or market areas. The three most important producers are General Electric, Borden, and Dow.[35]

The printing ink industry has long had a very low degree of innovation, but recently a new process and new products have been developed. Previously, inks dried on the paper as a solvent evaporated. But now ink is being "cured" with infrared heat. Unlike most firms in the industry, the firms developing the new technology and products are not simply blending existing ingredients--they are developing new chemicals.

There are two types of cellulosic man-made fibers -- rayon and cellulose acetate. Both have been produced for more than half a century and there appears to be no chemical innovation in this industry. Autex, Couralds, and Akzona are the leading producers of rayon, and Eastman Kodak and Celanese are the leading producers of acetates.

Cleaning and polishing compounds include bleaches, scouring cleaners, alkaline and acid cleaning compounds, disinfectants, and waxes. This industry is highly diffuse: there are over 1,000 manufacturers and fewer than 30 operate nationwide. Some of the leading firms are Economics Laboratory, S.C. Johnson, Chemed, and National Chemsearch. Most of the firms produce a few of the product types included in this industry.[36] Innovation in this area involves the development of new formulations and mixtures. The industry does make use of new chemicals which are developed elsewhere (primarily surfactants), but no chemical innovation occurs in the industry itself.

The paint industry is not expected to give rise to much innovation in the long run. New paints are new mixtures of existing products or of new products developed in other industries. We are currently witnessing a shift from solvent-based to water-based paints, but innovation associated with this shift is viewed as short-term. The industry is relatively unconcentrated, although concentration has been increasing. The top eight producers had 33 percent of the market in 1972, and 44 percent of the market in 1977. There were over

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[35] Meegan, Kline Guide, pp. 134-135.

[36] Ibid.

1,200 paint manufacturers in 1977, a decrease of about 20 percent in the last 15 years. Leading producers include Sherwin Williams, DuPont, PPG, SCM, and Mobil.[37]

The explosives industry is a mature one, and production is highly concentrated. The three largest producers (DuPont, Hercules, and Atlas Powder) produced 66 percent of the industry output in 1977, and the top eight firms produced 83 percent.[38] There is relatively little fundamental innovation in this industry. The innovations that have occurred have been process innovation and relatively minor improvements and refinements which increase safety.

Carbon black is a single element, carbon. There is no innovation in this industry.

INNOVATIVE SEGMENTS IDENTIFIED

From the summaries and the detailed analyses provided in Appendix E, it is apparent that historically only a few sub-segments are highly oriented toward new chemical entity introduction. These are catalysts, surfactants, and miscellaneous synthetic organic chemicals. In addition, there are several sub-segments in which new chemical entities are frequently produced. These are cyclic intermediates, rubber-processing chemicals, plasticizers, adhesives and sealants and plastics and resins. Finally, two segments which have recently become much more innovative are industrial inorganic chemicals, NEC and printing ink.

As shown in Exhibit 6-1, this list differs from ADL's in two aspects. First, there are some segments ADL did not consider highly innovative that ICF did. Second, ICF did not consider some segments innovative that ADL did. The segments considered innovative by ICF, but not by ADL, were cyclic intermediates, rubber processing chemicals, plasticizers and adhesives and sealants.[39]

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[37] Meegan, Kline Guide; U.S. Department of Commerce, 1978 U.S. Industrial Outlook (Washington, D.C.: Government Printing Office, 1978); U.S. Department of Commerce, 1972 Census of Manufacturers; and U.S. Department of Commerce, 1977 Census of Manufacturers.

[38] Meegan, Kline Guide, p. 149.

[39] ICF also thought printing ink and some elements of "salts, essential oils, and other chemical preparations, NEC" were innovative. They were not included in the analysis because (1) new product development in the elements of "salts, essential oils, and other chemical preparations, NEC" is limited to a very small portion of the industry and is not important to success in the business; and (2) the burst of innovation in the printing ink industry is the result of a recent major breakthrough in the underlying technology; this surge of innovation will probably be short-lived and the industry will no doubt return to its historically low level of innovation.

EXHIBIT 6-1

INNOVATIVE CHEMICAL SEGMENTS

ADL[a/][b/]	ICF and ICF Industry Experts
Surfactants	Surfactants
Catalysts	Catalysts
Miscellaneous Synthetic Organics	Miscellaneous Synthetic Organics
Industrial inorganics, NEC	Industrial inorganics, NEC
Plastics and resins	Plastics and resins
Synthetic rubber	Synthetic organic dyes and pigments
Organic fiber, non-cellulosic	Cyclic intermediates
Toilet preparations and perfumes	Rubber processing chemicals
Soaps and detergents	Plasticizers, adhesives and sealants

[a/] SOURCE: Arthur D. Little Incorporated, Impact of TSCA Proposed Premanufacturing Notification Requirements (Cambridge, Mass.: December 1978), p. III-4.

[b/] Segments considered highly or moderately innovative by ADL.

The segments considered innovative by ADL, but not by ICF, were soaps and detergents, synthetic organic dyes and pigments, toilet preparations and perfumes, synthetic rubber, and non-cellulosic organic fibers. Soaps and detergents, non-cellulosic organic fibers,and synthetic rubber all produce many new products each year; but these new products are usually just different formulations of existing products, or they incorporate new chemical entities produced by other chemical industry segments (surfactants, plasticizers, rubber-processing chemicals). There is some current innovative activity in the synthetic organic dyes and pigment segment, and EPA has received a comparatively significant number of section 5 notice submissions for chemicals in this segment. However, much of the innovation involves mixtures of existing chemicals, not subject to the notice requirements; and the number of section 5 notice submissions received under an as yet undefined, highly uncertain regulatory program cannot be used to draw conclusions about long-term trends. Finally, toilet preparations are not subject to TSCA.

Competitors in Innovative Segments. The three most innovative subsegments--catalysts, surfactants, and miscellaneous synthetic organic chemicals--are all characterized by a few large companies, with relatively small market shares and with numerous small firms. The specific firms clearly active in these markets are: Engelhard Minerals & Chemicals, American

Cyanamid, W.R. Grace, Air Products, UOP, Matthey Bishop, Filtrol, Kewanee Industries, Union Carbide, Girdler, Nalco, all the major oil companies, Monsanto, Witco, Proctor & Gamble, Borg-Warner, GAF Corporation, Jefferson Chemical, Rohm & Haas, Schenectady Chemical, BASF Wyandotte, Diamond Shamrock, ICI, Stepan, Alcolac, Emery Industries, Glyco, Miranol, Henkel, Longa, Millmaster Onyx, Mona, Quaker Chemical, Lever Brothers, Colgate-Palmolive, and DuPont. In addition, hundreds of smaller companies are very active in the surfactant and miscellaneous synthetic organic chemicals segments.

Each of these companies takes a different view of the importance of innovation to its survivals. For some, the introduction of new chemical entities is the "lifeblood" of the firm, while for others, new chemicals are a necessary adjunct to the basic product line. Nevertheless, all chemical firms appear to be innovative in at least one segment.

The size of firms is an important factor in identifying competition in these segments. Therefore, with the aid of industry experts, ICF developed Table 6-1 which shows, by sales volume and segment, the number of firms and their expected gross margins on new chemicals.

TABLE 6-1

ESTIMATED GROSS MARGIN ON SALES EXPECTED FROM THE HIGHLY INNOVATIVE SEGMENTS AND ESTIMATED NUMBER OF COMPANIES IN EACH SEGMENT

Annual Sales Volume of Firms	Surfactants	Catalysts	Cyclic Intermediates	Rubber Processing	Plasticizers	Synthetic Organic Chemicals, NEC	Adhesives & Sealants	Printing Ink	Industrial Inorganic, NEC	Salts & Other Chemical Preparations, NEC
0-3m	35 35%	10 50%	≈0 40%	0 35%	5 35%	500 35%	20 35%	0 35%	150 50%	50 50%
3-10m	20 30%	10 50%	120 40%	5 30%	20 30%	300 30%	40 30%	5 30%	150 50%	150 50%
10-200m	10 25%	10 40%	150 40%	15 25%	20 25%	150 25%	100 25%	10 25%	175 40%	150 50%
>200m	10 20%	20 30%	30 40%a/	20 20%	20 25%	50 25%	50 20%	5 20%	50 30%	50 50%
Total # Firms in Segmentb/	75	50	300	40	65	1,000	210	20	525	400

KEY

# of companies that carry out chemical reactions.

Gross margin on sales.

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a/High R&D expenditures.

b/Only manufacturers of new chemical entities.

SOURCE: Consensus opinions of panel of industry experts assembled by ICF Incorporated, June 1980.

CHAPTER 7

MEASURING THE IMPACT

In Chapter 2 we proposed a methodology to analyze and measure the impact of the premanufacture notice rules. The methodology required that we develop data on production, sales and use, price, substitutability, financial condition, foreign trade, and engineering, for various segments of the chemical industry. From these data we were to develop assessments of the market concentration, degree of integration, competitiveness, capital structure, and demand and supply determinants. (These assessments are shown in Appendix E.) The methodology then required the development of a demand forecast and a complementary supply forecast. The costs of the section 5 notice requirements would then be applied and changes in demand and supply would be measured.

The steps outlined in the methodology were:

1. Identify the number of new chemicals introduced in a segment annually,

2. Identify the costs of section 5 notice requirements for an individual new chemical product,

3. Perform discounted cash flow analysis of a representative sample of new chemicals with and without the costs,

4. Calculate the percentage of new chemicals that would not be introduced because of the section 5 notice costs, and

5. Translate the percentage reduction in new chemicals introduced into an economic impact measured in terms of GNP, unemployment, balance of trade, and other similar factors.

In performing the tasks, several theoretical and empirical problems developed.

Step 1

The first problem was that previous estimates of the number of new chemical entities introduced annually were not broken down in sufficient detail to allow segment-specific projections. This meant that any analysis would have to focus on broader segments in which there are usually some subsegments that are highly innovative and others that are not. Consequently, the analysis would be less precise than had been desired.

Step 2

As explained in Chapter 5, the costs of the section 5 notice requirements that are most significant are the ones that cannot be quantified. These were the costs of uncertainty concerning restrictive action, trade secret disclosure, and delay stemming from requests for additional information.

Step 3

Without representative segment-specific data and without fully quantifiable costs, any application of discounted cash flow techniques was limited.

Discounted cash flow analysis (DCF) is a technique the business community uses variously to evaluate investment opportunities. The concept requires that annual cash flow returns from a project be discounted at the marginal cost of capital to yield a value from which the required investment is subtracted. The difference is called the net present value. If the net present value is greater than zero, the project is profitable.

ADL used DCF techniques in its preliminary paper published in December, 1978. (See Appendix C for a summary.) ICF was able to develop an alternative set of results (also presented in Appendix C) using additional data and taking into account depreciation costs and the after-tax cost of the section 5 notice -- two factors ADL did not consider. Also, ICF was able to perform some sensitivity analysis that was not done by ADL. The sensitivity to discount rates -- one of the several sensitivity analyses performed -- was the analytical tool used to learn how uncertainty costs might be considered in corporate decision-making. As Appendix C shows, adding the factors ADL neglected yields very different results.

Step 4

Without DCF to predict how many new chemicals will be kept off the market by section 5 notice requirements, an analyst can only measure this decrease of relying on estimates from independent industry experts or participants in the segments. The independent industry experts ICF consulted felt it was not possible to measure the decrease _ex ante_. Many industry participants have suggested widely different estimates of the decrease. For example, the Adhesives Manufacturer's Association noted in response to requests for information from ICF that only one new chemical entity had been offered to its sample of members during the past year and that this was much lower than in the past. On the other hand, if section 5 notices submitted to date were an indication of the rate of innovation, then high polymer producers have shown no sign of a decrease in innovative activity. Finally, some industry experts and participants maintain that a shift is taking place from "unsafe" to "safe" chemicals and that during this transition there will be a temporary lull in innovative activity.

In light of the varying best guesses and without the ability to apply DCF techniques to a representative sample of new chemicals, ICF cannot predict a quantified level of reduction in new chemical introductions.

Step 5

If the necessary data were available and if costs linked to uncertainty could be accurately figured, it would be possible to estimate the number of chemicals introduced in the past that would not have been introduced because of the impact of Section 5 notice requirements. But it would still not be possible to measure quantitatively the broader economic impacts because, as explained in Appendix B and in the next chapter, there is no theoretical or empirical basis, without making unfounded assumptions, for translating changes in the introduction process of new products into quantitative economic models.

Summary

Major shortcomings were caused by the inability of formal analytical techniques to cope with non-quantifiable costs and by the unusual points of impact of such costs. As a result, the only way to consider the economic impact of the section 5 regulations is to make a qualitative assessment of the likely impact of a reduction in the number of new chemicals introduced in the innovative segments. This assessment is presented in Chapters 8 and 9.

It is important to note here, however, that the availability of data on historical innovation patterns by industry segment would have made the qualitative assessments less general. Such information is not available to us at this time.

CHAPTER 8

MODELS OF INNOVATION IN THE CHEMICAL INDUSTRY

To measure qualitatively the impact of the section 5 notice program requires identifying how the innovation process within a firm works and what impact the innovation process has on the firm and the economy. This chapter discusses the available literature on the innovation process and narrows the definition of innovation to include only new product development. We then describe three models of the innovation process based on empirical data and a fourth model that incorporates all of the activities that are part of the innovation process and that may be affected by the notice requirement. In conducting the literature review, ICF drew heavily upon a preliminary working paper done by ADL which is summarized in Appendix B. This was augmented by our own review of public materials and by a conference on chemical innovation at which five industry experts provided additional thoughts. (Appendix B expands on the discussion in this chapter and assesses the feasibility of developing computer models to measure the impact of the section 5 notice program.)

SUMMARY OF LITERATURE

There are four primary bodies of pertinent literature:

(1) The formal micro-economic literature on industrial innovation. Neoclassical growth theory has struggled for many years to deal with technological change. In the 1960's economists developed a means of incorporating technical change in the neoclassical growth model as the "theory of induced innovation"--but in a very formal manner of little use in this task. The theory does not help us because, first, it deals with what we would call "process innovation"--changes in the prices and quantities of input factors for given outputs.[40] New product development generally falls completely outside these theories.

Another problem is that until recently the theory has been developed largely at a macroeconomic level. Also, there seems to be little theory in the economics literature on the role of uncertainty in the innovation process--either at the firm level, industry level, or macroeconomic level. It is possible to distinguish between "technical uncertainty" (the uncertainty that the scientific and engineering development process will produce something of potential use) and "market uncertainty" (the uncertainty about the degree of demand for a product in the future and about how actions of competitors may affect payoffs). It is also theoretically possible to model "technical uncertainty" through a probability cash flow model, "market uncertainty" through a game-theoretic approach, and the two together through incorporation into a portfolio-choice capital budgeting model for R&D expenditures. But there is almost no body of microeconomic theory to rely upon, as there is in areas of industry and firm behavior.

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[40] Even here, there is much confusion and apparently no clear way empirically to separate movement along an isoquant (factor substitution) and shifts in the isoquant (technical change). Because of the difficulty in separating the two (in either case, the optimal factor ratio changes in favor of more use of the less expensive factor), several economists have recommended abandoning the distinction entirely.

It is worth noting that economists are now moving into this field in an attempt to extend the current body of theory. Nevertheless, at the present time, economic modeling of product innovation (quite apart from the even more difficult issue of section 5 notice impact on that innovation) places us at a frontier of economic theory without tested or accepted approaches upon which to rely.

(2) Empirical studies of innovation. There are extensive studies, generally at the industry level, which attempt to analyze and understand the industrial research and development process. These range from studies which are quite analytical and use formal models and actual historical data (usually time-series or pooled time-series/cross sectional multiple regression analysis) to qualitative case studies. Industries covered are primarily drugs, chemicals, glass, steel, or petroleum. Attempts are made to relate the amount of R&D expenditures to a wide variety of firm and industry parameters and to relate "outputs" such as sales of new products to amounts of R&D expenditures. Despite the recent work of Mansfield, Nelson, Iverstine, and others, there is a paucity of empirical detail on the resource allocations to the various stages of the R&D process, on how and why firms make R&D allocation decisions, on how firms evaluate R&D expenditures, or on how firms (in a game-theoretic sense) decide what to patent or bring to market. As discussed below (and in the ADL survey), this literature provides some ideas about the determinants and decision-making in the R&D process, but the bulk of it is not very useful for several reasons:

- It is based upon old data (1954-1959) and thus upon structural and societal relationships and forces which arguably no longer pertain.
- It is conflicting in many of its findings.
- It is often based upon questionable data and surrogates for innovation (due to lack of useful data) and at rather high levels of aggregation, even at the large company level, there are many very different "businesses" being aggregated.
- There are few studies of the chemical industry and few significant conclusions from these studies.

(3) Specific studies on the effects of government regulation on innovation. There have been reasonably extensive studies of the impacts of the 1962 Amendments to the Food, Drug and Cosmetic Act on innovation in the pharmaceutical industry and less extensive studies on the effects of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) on the pesticides innovation process. As discussed below, although these studies highlight some areas of interest to TSCA, there is little of use here, either:

- the studies are generally post hoc analyses with single equation approaches or international comparisons, neither of which is particularly helpful to TSCA's need to develop a method to assess impacts ex ante;
- the studies deal with regulations very different from notice requirements (and different from TSCA more generally); or
- the studies are data constrained, in some cases use questionable surrogates for innovation, fail to separate the regulations themselves from concurrent societal forces, and provide little data on how regulations have affected R&D decision-making by firms.

(4) Studies from the "business literature". There is a growing literature on R&D, innovation, and technical change arising from managerial sources, which provides some useful empirical insights. The literature ranges from studies of R&D strategy to the extensive work done on capital budgeting, decision-making under uncertainty (particularly Bayesian statistics), and portfolio/risk theory. Although these provide useful grounds upon which to model certain business decision-making, much of this literature is too abstract and complex to be applied to the variety of common business decisions: there remains a significant gap between the case studies of individual firms and a formal analysis of a business decision made under uncertainty. Yet, the need to understand the effects of notice requirements on the chemical industry remains, but the literature discussed previously in (1), (2), and (3) is of little use. In conclusion, if we are going to learn how notice requirements affect the decisions made by the chemical industry, we must ascertain first how and why chemical industry officials allocate R&D resources, assess probabilities, and make decisions about development and commercialization.

LITERATURE REVIEW

We have noted in the summary above that the existing literature has little to offer in developing a formal approach to analyze the impacts of notice requirements on the chemical industry. Because of this, and because the literature review in Appenxix B is generally thorough, this section is a brief summary. Numbered citations in the text refer to the bibliography in Appendix B.

There are four areas of the literature:

(1) Microeconomic Theory of Industrial Innovation,

(2) Empirical Studies of Innovation,

(3) Specific Studies of the Effects of Government Regulation on Innovation, and

(4) "Business" Literature.

Microeconomic Theory of Industrial Innovation

In this category, the review by ADL is more than adequate; therefore, the conclusions documented in Appendix B are summarized and restated:

- The theory of induced innovation that is incorporated into neoclassical growth models addresses only process innovation.
- Research and development costs are seldom even included in models; when they are, there are serious difficulties. Economists argue about whether or not a firm can choose the direction technical innovation will take; some believe that to admit that firms can control the rate or direction of technical change means abandoning competitive models.
- Most past efforts have been in a macroeconomic framework.
- Existing models do not deal either with technical uncertainty or market uncertainty or with how allocation decisions would (or should) change with changes in these factors. TSCA regulation is expected to affect both technical uncertainty (by increasing the number of technical criteria a product must respond to) and market uncertainty (by adding costs, increasing delays, weakening competitive position, reducing payoffs, etc.); there is no systematic means to deal with these regulatory effects in these models.

Empirical Studies of Innovation

Conclusions in these studies are often contradictory. The question of how diversification affects innovative activity is a good example of such a contradictory finding. Grabowski finds a positive effect, Scherer finds no systematic effect, and Weiss finds a negative effect. Even when there are findings--that R&D intensity, as measured by R&D employment regressed against sales, tends to rise with firm size in the chemical industry--there are no straightforward implications for the task at hand.

Here are some broad findings from this literature:

- At the firm, industry, and economy level, there is high correlation between R&D expense and economic growth/ productivity. The ADL report cites R&D intensity as a "source" of growth (although it notes that causality may run in both directions); more conservatively stated, high R&D is associated with high growth and positive changes in productivity.
- Chemical industry R&D intensity appears to rise with firm size, yet R&D per sales dollar is higher with smaller firms.
- There is no consensus on the relationship between innovative activity and industry concentration or degree of product differentiation.
- Several studies suggest after-tax average returns on R&D capital of 15 to 20 percent.
- One expert (Kamien) estimated that more than three-fourths of U.S. industrial R&D was directed toward new products rather than new processes.

Specific Studies of the Effects of Government Regulation on Innovation

ICF looked closely at the previous work in the pharmaceutical and pesticides industries because, despite its *ex post* nature and regulatory differences from TSCA, the general approach they used at least addressed directly the relationship between regulation and innovation. Thus, the following section provides a little more detail than the previous two summary sections; without doubt, TSCA will be subject to analyses like these in the future.

This summary of the literature is a brief guide to the effects of regulation on innovation in the pesticide and pharmaceutical industries and how these effects may relate to the chemical industry. References are made to major empirical studies in the bibliography in Appendix B.

The Pharmaceutical Industry

A number of studies have been done on the effects of the 1962 Amendments to the Food, Drug and Cosmetic Act on innovation and R&D in the pharmaceutical industry. The most significant findings are summarized here in terms of the following four hypothesized impacts of regulation on innovation. Regulation:

(1) lowers return on R&D due to increased costs, risk, and development time associated with regulatory compliance and leads to a lowered rate of investment in R&D and potential decline in innovation;

(2) changes the pattern of R&D and innovation (e.g., away from basic research to emulative products or from product to process innovation);

(3) changes market structure which may affect the rate and pattern of innovation; and

(4) promotes international transfer of resources and technology from countries with strict regulatory requirements to those with less strict requirements.

Level of Innovation. Based on Baily's study (7) showing an increase in new drug discoveries resulting from increased R&D expenditures, several authors have investigated the expected rate of return on pharmaceutical R&D investment (19, 83). Schwartzman, for example, finds a drop in the rate of return from 11.4 percent in 1960 to 3.3 percent in 1972 due to increased costs posed by federal regulation.

Hansen (38) estimates a development cost of $54 million (1976 dollars) for a new chemical entity (NCE) and about nine years for the NCE to reach the market. Many others have documented the decline in introduction of NCE's since 1962. (See 43, 55, 75, 91, 92.) The exact portion of that decline directly attributable to regulation is, however, still open to question.

Both Baily (7) and Peltzman (75) find a statistically significant negative effect of regulation on the number of new chemical entities introduced in the U.S. after 1962, but serious criticisms of these empirical models exist. For example, Baily's supply-side model ignores the effects of changes in demand, and both Baily and Peltzman neglect to provide an adequate measure of "research depletion" or to explore the possibility that any exhaustion of research opportunities actually existed.

Using a comparative analysis of the British and American cases to get at the same issue, Grabowski, Vernon, and Thomas (32) find a six-fold decline in R&D productivity in the U.S. between 1960-1961 and 1966-70, compared to a three-fold decline in the U.K. in the same time period. The difference between the two countries may be part of the well-known "drug lag", suggesting that it was the particular legal and institutional form of regulation in the United States that has been most responsible for negative effects on innovation.

As for the three-fold decline in the U.K. rate, it is again not possible to distinguish the effects of increased regulation in that country from research depletion or from changes in demand due to a different social and medical context.

An Arthur D. Little paper (4) emphasizes the importance of a simultaneous equation approach to modeling innovation in the drug industry, rather than single-equation models which model either the supply side or the demand side, but not both together. The 1962 legislation in the U.S. (and regulation in other countries) was one aspect of a change in attitudes directly related to the thalidomide incident which arguably affected demand for new drugs. On the supply side, the possibility of exhaustion of research opportunities, perhaps due to gaps in scientific knowledge, is an important and controversial issue that has not been effectively addressed in econometric studies of this subject.

Type of Innovation. The position taken by the FDA is that the decline in new drugs since 1962 has been a result of the focus on new chemical modifications of existing drugs, rather than the result of inhibiting new therapeutic advances. This position is a controversial one both factually and in its tacit assumption that society has not lost much from the decline in slightly modified drug products. The nature of new drug innovation is dealt with in several sources (see 39, 75, and 82).

Market Structure. A great deal of literature has dealt with questions of market structure and innovation in the pharmaceutical and in several other industries. Most writers have explored the relationship of firm size to innovation in an attempt to assess empirically Schumpeter's hypothesis that large firms are associated with greater inventive output (81). (See, for example, 5, 12, 24, 35, 37, 59, 79, 82, and 89.) It appears that there is still little consensus on the validity of this hypothesis.

Kamien and Schwartz (46) provide a useful survey of research done on this question which takes into account the two aspects of the "scale" issue: the effect of firm size on efficiency for a given size R&D facility and the efficiency of different sized R&D facilities within a firm. More recent studies have investigated the effects of rivalry on the innovation process (31, 47, 66).

As in the pesticide industry, active ingredient R&D on pharmaceuticals is conducted by a limited number of firms (approximately 100) and is generally confined to the larger companies because of high development and testing costs. One study finds that, although some increased concentration has been evident in innovation among the larger firms since 1962, the innovational role of the small firms that do perform R&D has diminished only slightly (73).

International Transfer. A fair amount of evidence has been amassed to indicate that since 1972, pharmaceutical innovation has shifted from the U.S. to countries abroad -- a shift due to differential regulatory requirements. The pharmaceutical industry has a strong multinational component, so that a shift in R&D and production can be easily accomplished. It is difficult, however, to distinguish the effects of regulation on this trend from other cost-related factors. (See 32, 33, and 73.)

The Pesticide Industry

Very little literature exists on the effects of regulation on innovation in the pesticide industry. The primary sources of data are the industry surveys made by the National Agricultural Chemicals Association (69). These surveys, however, vary from year to year in the number of firms participating and the categories used, so that a detailed analysis of trends in innovation is not always possible. Some idea of recent patterns in the industry can, however, be gleaned from the NACA data and other sources.

Expenditures on pesticide research and development have continued to rise in the last decade, keeping pace with the increase in pesticide sales. The cost of bringing a new chemical to the market, though, has risen from estimates of $5.5 to $6 million in the early 1970s to a current estimate of $15 to $20 million (including the cost of unsuccessful compounds). Total elapsed time from discovery of a pesticide to marketing has also been increasing from an average of 60 months in 1967 to 110 months in 1977. Although the share of R&D funds spent on discovery and commercialization of new products has been roughly constant in the last five years (near 65 percent), a much higher proportion of R&D expenditures is now devoted to regulation-related activities. The result is that fewer new commercial products have been forthcoming, and it is assumed that the number of annual new registrations of active ingredients with EPA will not exceed 10 to 15 in the near future.

Unfortunately, no precise linkage of the changes in pesticide innovation with the effects of FIFRA regulation is possible. The pesticide industry is relatively mature (70) and it is generally believed that most major markets have already been filled with effective products, though product obsolescence is common in the industry. On the other hand, registration requirements have probably exacerbated the trend toward increasing modification of existing pesticides for new uses rather than developing new chemical entities.

There is, in addition, a wide variety of anecdotal evidence that direct and indirect effects of regulation have hindered both the development of products for minor crops and uses and innovative work in the development of biological alternatives to chemical pesticide control. It is believed that the few small firms that are involved in pesticide R&D have been involved in some of this innovative work (23). The effects of regulation on market structure, although limited, may therefore be indirectly injurious to some sources of innovation.

The Chemical Industry

The relevance of the experience of the pesticide and pharmaceutical industries under pre-market regulation to the effects of TSCA on the chemical industry is severely limited. The methodological problems in previous studies restrict their use in studying the chemical industry. There are also substantive differences among the industries.

Pesticides and pharmaceuticals are not typical segments of the larger chemical industry. The levels of R&D conducted in the industries differ significantly, (about 10 percent of sales in pharmaceuticals, eight percent in pesticides, and two to four percent for chemicals). Although we do not have enough data on the chemical industry to be certain, we suspect that other important differences exist as well. Examples are the expected value of sales of new products, the barriers to entry into R&D, and in general, the effect of firm size and scale of R&D facility on innovative potential (see 26 and 30). The comparability of the chemical industry to the pesticide and pharmaceutical industries on two matters -- the role small firms play in each and the research opportunities each enjoys -- could also modify the effects of regulation on the industry.

Variations in the regulatory process that different industries undergo may also be important. Premanufacture notification does not require specific testing and has an established review period of 90 days (may be extended to 180 days), unlike the FIFRA pesticide registration program and FDA's Investigative New Drug (IND) approval system. Similarly, the treatment of confidential information in the regulatory process may affect not only the rate of innovation but the type of innovation (i.e., development of either subtle variations on existing chemicals or entirely new types of chemicals) and the location of activity.

Measurement of innovation appears in the literature on pharmaceuticals as a serious obstacle to empirical study. The problem is aggravated in the case of the chemical industry, where even the annual number of new chemical entities introduced is unavailable from a single authoritative source. Some of these issues are dealt with in (52), (66), (78), and (79).

For these reasons, it is not likely that the major studies done on the pharmaceutical industry or the experience of the pesticide industry can be easily extrapolated to predict TSCA's effect on the chemical industry. No doubt some of the determinants of innovation in the industries will be common. However, it is not our expectation that the results of regulation in the chemical industry as a whole will conform to the results in two of its rather atypical sectors. For example, the nature of R&D in both pharmaceuticals and pesticides centers on product rather than process -- not so for at least the high-volume segments of the chemical industry; most new products (active ingredients) in the former cases are expected to penetrate large markets and have development costs of $20-30 million over the course of five to 10 years.

This calls attention to the heterogeneity of the chemical industry and the need to disaggregate the various sectors it encompasses. It appears that pesticides and pharmaceuticals are at one end of the spectrum of chemical industry subgroups in terms of innovation. As explained later, other patterns of innovation and of regulatory effects on innovation are more characteristic of the chemical industry in general.

The "Business" Literature

Apart from the extensive theoretical literature on capital budgeting, decision analysis under uncertainty, and portfolio risk analysis, the business literature also contains examinations of individual firms or innovations and behavioral studies relating organization and management approaches in R&D to successful results. Both these approaches look carefully at actual firm performance and have produced the following conclusions:

- The bulk of R&D projects in large chemical firms are relatively safe from a technical point of view (59).
- Expected rates of return (if successful) were about 30 percent--arguably about the same, after probability adjustments for some failures, as other capital investment (59).

- Firms devoted about nine percent of R&D funds to "basic research," 45 percent to "applied research," and 46 percent to "development" (60).
- Even for research-intensive industries like chemicals, innovations are often based upon technology or research derived from organizations other than the innovating firms (68).
- There is considerable anecdotal evidence that in significant parts of the chemical industry--especially for small firms and in the specialty chemicals area--a great deal of product innovation is closely tied to customers and the market (i.e., there may be little or no "market uncertainty").
- There has been considerable development of the product life-cycle theory which may have application in longer-term modeling of new chemical products.
- In case studies of successful new product innovations with major impacts, factors cited (49, 76) as significant (ceteris paribus) in promoting innovations are:

	Effect on Innovation
-- firm size	+
-- relative R&D spending: firm to industry	+
-- industry growth rate	+
-- stability of industry in terms of structural products	-
-- degree of involvement of R&D groups with potential users	+
-- degree of status, authority, and involvement of top R&D manager with the project	+
-- in-house initial support for the innovation on commercial grounds	+
-- relative sales effort for the new product, including publicity/advertising	+

MODELS OF INNOVATION

The ICF analysis identified four models of innovation in the chemical industry. Three of these models are typical of different size firms. The fourth model, which is a theoretical model, was developed on the basis of the literature and the other three models. The models explicitly incorporate different types of R&D decision-making as the basis for modeling the innovation process.

Three Models Based on Firm Size

During the meeting of industry experts convened by ICF, considerable attention was directed to the importance of firm size in understanding new product introduction decision-making and, therefore, section 5 notice requirement impacts. Numerous schemes for categorizing firms by annual sales volume have been proposed. SOCMA, in a presentation to EPA staff, defined a small firm to be one with annual sales of $30 million or less. However, their categories were not designed to look specifically at new product introduction decision-making. The industry experts described four categories of firms based on annual sales volume which were targeted at understanding innovation. The four sizes were:

1. $0 to $3 million,
2. $3 to $10 million,
3. $10 to $200 million, and
4. greater than $200 million.

Characteristics of Firms in Each Category. The smallest firms include the industry entrepreneurs. These firms usually are started as university spin-offs or by employees of large firms who decide they want to try it on their own. Several hundred firms start this way annually and most of them fail. If after a few years the firm has not reached the $3 million level, it will most likely cease to exist.

The second category is the $3 to $10 million firms; these are the entrepreneurs who have become successful. They, like the smaller companies, typically have one key person who is the "research and development," "marketing," and "operations" executive.

The third size category of firm is the $10 to $200 million operation. In this category will be found companies which have become too large to have only one decision-maker. They are beginning to develop organizational divisions with special tasks (R&D, sales, etc.). The mix of product sales volumes in these companies will vary from $2,000 for some new chemicals to several hundred thousand dollars or more for most mature products. Occasionally these firms will have some products that sell over a million dollars a year. These firms are frequently characterized by defensive marketing strategies for new chemicals -- strategies that are based on fear of competition from industry giants and that may have consequences for section 5 notice requirements.

The companies with a sales volume greater than 200 million a year are the industry giants. These companies are usually organized into divisions or departments based on product markets. They usually have a small basic research unit at the corporate level and numerous applied research units within the operating divisions. The basic research group at headquarters works on chemicals that might not be commercialized for 20 years. The applied groups are always seeking new products for current markets. Many of these companies also have commercial development units which link events in the marketplace to R&D projects that should be funded and thereby identify new business opportunities. These groups usually consist of both sales and R&D personnel. By interacting with the customers to discover their needs, the group is able to identify what characteristics a new chemical must have to be successful. Using this information, the applied R&D unit in the division then creates such a chemical.

New Product Development Models. In these large companies, formal mechanisms allocate resources to R&D and formal processes choose among R&D projects. In many of the industry giants the decision-making committee meets many times a year. At these meetings they assess the status of the current projects from a technical viewpoint. They review the economic and financial aspects of the projects, and then they decide which projects to continue to fund in what amounts. Formal financial analysis plays a much greater role in the process in this size company than it does in smaller companies because the financial analysis is the means by which all sectors of the company communicate.

In the $10 to $200 million companies, decisions on allocating resources to R&D and on new products are made informally. Usually these firms have an executive in charge of R&D projects who meets with an Executive Commmittee to make decisions about (1) how large an R&D budget to have; (2) what R&D projects to fund; and (3) what projects to commercialize. This committee does not usually base its decisions on formal financial analysis, because such an analysis is not necessary for communication. These firms are not large enough to have commercial development groups or to afford basic research. Almost all new chemical introductions result from a talented researcher or from a customer's specific request.

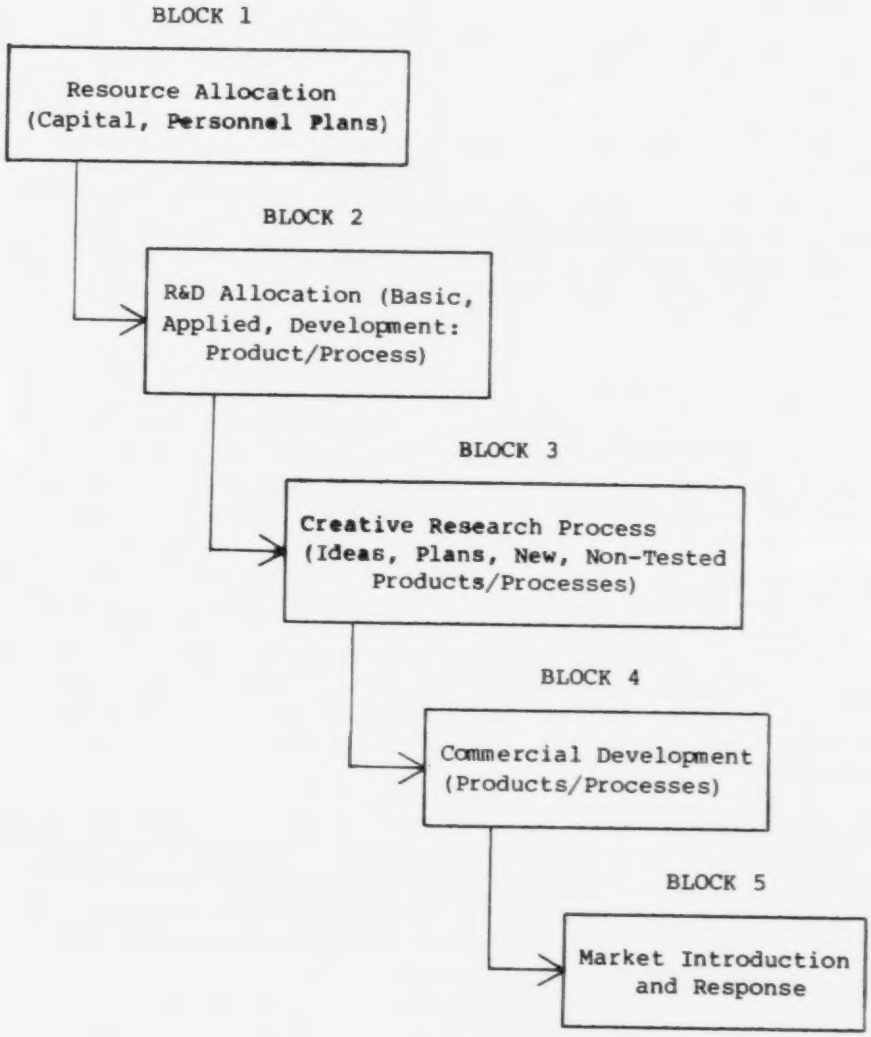
In the smallest firms (under $10 million in annual sales), the new chemical introduction process is usually based on the entrepreneur's technical skill. The entrepreneur does not have any formal processes for deciding how to allocate resources. In the course of managing daily operations, he makes these decisions implicitly. Nevertheless, the repartition of time among sales, operations, and research reflects the relative returns expected from these efforts. Thus, the entrepreneur indirectly makes resource allocation decisions.

Theoretical Model. Each of these empirical models can be accommodated in a theoretical model which is presented in Exhibit 8-1. The model identifies five blocks of activity in the new chemical development process. These activities are: (1) resource allocation to R&D; (2) R&D allocation to specific products; (3) creative research process; (4) commercial development; and (5) market introduction and response.

It appears evident from the diverse literature addressing this process that each block of activity in the theoretical model may be distinct and may be influenced by different factors. Further, the nature of the activity will vary widely depending upon which segment of the chemical industry is being considered and by the size of the firm within that segment.

EXHIBIT 8-1

INNOVATION PROCESS


BLOCK 1
Resource Allocation (Capital, Personnel Plans)
BLOCK 2
R&D Allocation (Basic, Applied, Development: Product/Process)
BLOCK 3
Creative Research Process (Ideas, Plans, New, Non-Tested Products/Processes)
BLOCK 4
Commercial Development (Products/Processes)
BLOCK 5
Market Introduction and Response

Outputs

- Sales
- Profits
- Substitution

Allocation of R&D Inputs (Block 1). The firm decides to allocate dollars, people, office space, contract monies, and other resources to research and development. Some of these allocations may be influenced by existing R&D projects or expenditures; may be required by specific market forces; may be a result of a formal decision process or a rule-of-thumb; may be done at various levels of explicitness; and may be on an annual or project budget. But the firm has a cost of capital and alternative allocation possibilities (capital investment, dividends, hiring, etc.). In a formal or informal manner, a decision maker in the firm is assessing the potential return from R&D in relation to other uses of capital.

Allocation of R&D Resources to Projects (Block 2). Possibly in combination with Block 1, on an incremental or total basis, somebody in the firm sets objectives, defines projects, and allocates resources to projects. These projects may be long-term or short-term; "basic", "applied" or "development" research, aimed at new products or processes or at cost reduction on existing processes; focused at a specific market opportunity ("demand-pull") or just an interesting product quality ("science-push").

The Research Process (Block 3). According to some organization and management rules or procedures, the project research proceeds. The activity could range from a scientist alone at a bench for months, to close work with a potential user, to work under contract at a university; it could be cost engineering rather than "science"; it could be managed in a wide variety of ways; it could be under intense time pressure or very loose; it could take days or years.

Commercial Development (Block 4). After the research process, a process change or a product is created. A decision is made as to whether and how it should be brought to market. Assessments will typically be made of the potential market, the likely cost of production, the possible market price, what the competition will do, the probability of success, timing, the firm's capital availability in relation to other opportunities, whether it can or should be patented (if it has not been in Block 3), and how it should be introduced or promoted.

Market Introduction and Response (Block 5). Initially, and over what may be a very long product (or process) life cycle, the product is produced and sold. Sales may go up, costs may decrease as volumes increase, a similar but inferior product may be driven from the market, prices may rise or fall depending upon demand and competition, and a host of impacts may be traced throughout the industry and economy.

CHAPTER 9

QUALITATIVE ANALYSIS OF IMPACT ON NEW CHEMICAL INTRODUCTIONS

In Chapter 8 we identified five blocks of activity important to the innovation process. Earlier we had identified three types of costs that chemical companies face. These are (1) direct out-of-pocket costs; (2) delays in the introduction of new chemicals; and (3) uncertainty regarding direct costs, length of delay, possible trade secret disclosure, and possible use restrictions. According to independent industry experts, testimony in the public record by affected interest groups, and the literature concerning the introduction of new products, economic impacts of section 5 notice requirements will result from these kinds of costs. This chapter summarizes the effects of proposed section 5 notice requirements on the introduction of new chemicals.

IMPACT ON COMMERCIALIZATION ACTIVITIES

The five blocks of activities associated with new product introduction and identified in Chapter 8 were resource allocation, R&D allocation, creative research process, commercial development, and market introduction and response. Notice requirements will increase the expected costs associated with Blocks 1 and 2. These greater costs will decrease expected returns from these activities, which will probably cause fewer dollars to be allocated to these blocks. Block 3 is presently being affected because companies are probably beginning to rule out certain toxic families of substances as potential products. Similarly, the out-of-pocket costs and uncertainty would clearly affect decisions about what to bring to market (Block 4). Impacts on Block 5 would be felt if notice data made public allowed competitors to bring alternative products to market more quickly.

The effect of the direct costs and uncertainties on Blocks 3 and 5 will not vary with the size of the firm. All firms can be expected to move toward innovation in "safe" chemicals. What constitutes a "safe" chemical depends on the state of chemical knowledge and EPA administrative practices with regard to various chemicals. All firms will also be affected by having some notice information publicly-available which would allow competitors to bring alternative products to market more quickly. The effects on Blocks 1, 2, and 4, will differ however, according to company size.

Large Companies

Independent experts have estimated that the major firms will not substantially change the direction or depth of their new product programs because of the costs of notice filing, so long as those costs are only a few thousand dollars. Yet, industry experts have also said that the imposition of the notice filing cost will, in aggregate, cause industry giants to reconsider the value of some R&D projects within new product programs (Block 3 impact).

Similarly, the uncertainty about EPA actions may cause at least a temporary hiatus in some R&D programs. In sum, for the large companies, independent industry experts have stated that the uncertainty costs will have a greater impact than the cost of filing the notice. One expert, a retired executive of an industry giant, believed that (1) the cost of filing the notice was *de minimus*, and (2) the large companies were already moving away from research in potential toxic fields, so that the effect of the final notice regulations on these companies would be nil. This view of uncertainty costs is not shared by others. As pointed out in Appendix C, it could be argued that, for very large volume-low profit or very high profit-small volume products (products typical of the industry giants), notice filing costs are of little significance to the decision process.

Mid-Size Companies

The impacts on Block 1, 2, and 4 for mid-size companies ($10 to $200 million annual sales) will be substantially greater. The key differences between this size firm and the giants are the expected sales volume of particular new products and the access to expertise about the government program. Both these differences will result in greater impacts on these smaller companies.

In the ICF meeting on chemical innovation, participants characterized these firms as being fairly uninformed about regulatory and legal matters. Without expertise in regulatory matters, they would likely choose to take actions that minimized their exposure to the threats posed by regulation. Thus, they should be expected to (1) steer their new product development away from suspected chemicals, and (2) minimize their regulatory and legal costs by simply not marketing any chemical on which EPA makes a request for additional data.

The second difference which will cause these medium-size companies considerable problems is the volume of sales of their new chemicals. Smaller chemical companies often obtain a portion of a large company's market when they introduce new chemicals. Small companies without extensive legal expertise may be unable to protect confidential information from being disclosed. Public notices may reveal information about the companies and chemicals. The notice process will therefore provide large chemical companies with an inexpensive way to track their small rivals' new product development. This knowledge will inevitably result in a competitive advantage for the largest companies. There is a second way in which this difference will hurt smaller companies. Their lower volume sales of new chemicals generate lower profits (though not lower profit margins) with which to absorb notice filing costs and uncertainty. (In Appendix C considerably more analysis of this aspect is provided.)

During the meeting of industry experts, a characteristic capital budgeting model for R&D commercial development decisions in this size firm was presented. It highlighted how the section 5 notice cost would affect decision-making on new chemicals. The model was an equation (shown below) which could be used to produce a value (PN) for each possible project under consideration by management. The projects receiving the highest PN's are the first to receive funding in any year.

The equation was:

$$PN = FC \times \frac{T \times R_C \times R_T \times R_{PMN} \times [V \times (\text{Price} - \text{Cost RM}) - LUD - TS]}{C_{RES} + C_{CD} + C_{PL} + C_{PMN}}$$

where:

PN = Project number.

FC = Volume factor.

T = Life cycle of products in years.

R_C = Probability of commercial success (0 to 1).

R_T = Probability of technical success (0 to 1).

R_{PMN} = Probability of chemical not being questioned by EPA.

V = Sales volume in pounds.

Price = Price per pound.

Cost RM = Cost of raw materials per pound at annual sales volumes.

LUD = Labor, utilities, and depreciation at annual sales volumes.

TS = Cost of technical service necessary on sales.

C_{RES} = Cost of research to develop chemical.

C_{CD} = Cost of commercial development.

C_{PL} = Cost of plant and equipment (if any).

C_{PMN} = Cost of filing notice.

As the equation reflects, prior to TSCA, the key concerns were the expected dollar volume, the probabilities of technical and commercial success, the gross margin on sales, and the costs of development. The equation would not have had the R_{PMN} and C_{PMN} entries. The section 5 notice requirements affect this equation by adding the additional uncertainty reflected as a probability of clearing the EPA review (R_{PMN}) and by addition of the cost of filing a notice (C_{PMN}). Both of these effectively reduce the value of PN thus making all investments less attractive. (The magnitude of the reduction is discussed in Appendix C.)

Small Companies

The very smallest firms in the industry (those with less than $10 million in annual sales) may feel these same two differences--lower expected profits on new chemicals introduced, and lack of regulatory expertise--even more than the medium size firms. Their small managerial staff and legal capability will cause their direct out-of-pocket and uncertainty costs per new chemical to be greater.

Summary

According to the industry experts, the process of developing new chemicals within a firm varies most directly with the size of the firm. Furthermore, the direct costs of the notice program and the uncertainties about release of confidential information and a possible EPA challenge of the chemical will affect smaller firms more than larger firms. As firm size increases, the cost of the notice filing becomes less important than the uncertainty about EPA's decision. These factors will be felt most in decisions to allocate funds to research and development, in choosing which projects to fund, and in beginning commercial development. In Appendix C a financial analysis of the extremely limited, and possibly misleading, available data is provided. In the next section we discuss how the impact on individual firm innovation will affect the chemical industry.

IMPLICATIONS FOR THE CHEMICAL INDUSTRY

The implications of the effects identified above vary by chemical segment. The segment-specific factors that will cause the impact to vary are

- innovativeness;
- structure of the segment;
- sales growth patterns;
- product mix (annual sales volume); and
- possible restrictive action.

Innovativeness

More inventive firms are likely to introduce more new chemical compounds than non-innovative firms. As a result, they will be more severely impacted by section 5 notice requirements.

Structure of the Segment

The industry experts identified four categories of firms based on annual sales volume. These categories were described in Chapter 8 and may be briefly characterized as follows

- $0 to $3 million--industry entrepreneurs;
- $3 to $10 million--successful entrepreneurs;

- $10 to $200 million--firms beginning to develop organizational divisions with special tasks; and
- greater than $200 million--industry giants.

As noted earlier, in regard to notice requirements, the structure of the segment is particularly important in evaluating firms in the $10 to $200 million category. These firms often will not bring to market a new chemical with tremendous potential market value because they fear that the industry giants will enter the business and capture so large share of the market that the smaller firms' investment will be lost.

Additionally, if a segment possesses a large number of small competitors and a handful of large competitors who have only small market shares, it is likely that the disproportionate impact of section 5 notice costs on smaller companies will result in increased concentration in the future. This could hinder economic efficiency in the segment.

Sales Growth Patterns

Expectation concerning rate of sales growth and lifespan of products will directly affect evaluation of a new product. Will it gain broad enough acceptance and stay on the market long enough to absorb the additional costs? Where expected sales volumes and lifespan are radically different--for example, organic dyes with small volumes and short lifespans versus inorganic acids with large volumes and long lifespans--the ability to absorb the costs will differ substantially. Generally, shorter lifespan or lower expected growth products will be more significantly impacted.

Product Mix (Annual Sales Volume)

The product mix is measured in terms of annual sales volume of the individual products of individual firms. There are various mixes -- large number of small volume products, a few high volume products, or some combination. If the future product mix is predicted to remain the same as today's, the ability of a firm to adequately absorb front-end costs is dependent on the volume and profit margin of products sold. Generally, firms which expect to introduce many small volume chemicals may be more affected than those which expect to introduce a few high volume chemical products.

Product mix varies across all sectors. It is more "general" than say, innovation, and the effects of product mix will be more widely felt than any other factor. To assess the relative impact on firms with different product mixes, we examined individual company data provided in response to the reproposal in 44 Federal Register 59764. Exhibit 9-1 gives a representative sample of sales distribution by volume as estimated by CSMA and as reported by four companies. Clearly, smaller volume products dominate the product mix, even for the larger firms. If we assume this distribution is externally valid, then on the average, the larger firm's process of developing products, but their not financial viability, might be affected just as severely as smaller firms. (Our independent chemical industry experts questioned the external validity of this data because it did not include enough large volume chemicals.)

As a result of notice cost imposition, there may be fewer chemicals introduced, and the "consolidation of product lines into high volume products" strategy may be taken by many firms. This will lead to a lessening of new products and could lead to tiering, where the likelihood of introduction of competing substances decreases and/or profit margins increase. However, this may or may not cause a lessening of overall sales growth and profitability for the sector as a whole.

EXHIBIT 9-1

SALES DISTRIBUTION BY POUNDS OF PRODUCT PER YEAR
(in percent of total sales)

		Pound Volume				
Company	Annual Sales ($ Millions)	Under 1K lbs.	1-10K lbs.	10-100K lbs.	100-250K lbs.	Over 250K lbs.
Reilly Tar	50-100	75	8	(	17	)
Pennwalt	480	34	18	14.5	2.2	31.3
Nalco	500	5	15	34	21	25
Dow Corning	500+	7	15	33	(45	)
CSMA	--	(	70	)	(30	)

Source: Responses from individual firms to 44 FR 59764, October 16, 1979.

Possible Restrictive Action

Firms will refrain from developing new chemical products in areas where production and/or use of the chemical is currently subject to government restriction. And they may refrain where they think a product likely to be a candidate for future regulation. Chemical companies, particularly small firms (less than $10 million), prefer to avoid operation in a highly regulated segment due to time delays, costs of dealing with the government, their inexperience with the government, and the uncertainty resulting from operation in a regulated area.

SEGMENT ANALYSIS

These segment-specific factors form the framework for discussing the likely effect the section 5 notice requirements will have on the innovative segments identified in Chapter 6--segments in which new product development is expected to be of continued importance to success.

These segments are

- Surfactants;
- Miscellaneous Synthetic Organic Chemicals, NEC;

- Cyclic Intermediates;
- Catalysts;
- Rubber Processing Chemicals;
- Plasticizers;
- Adhesives and Sealants; and
- Industrial Inorganic Chemicals, NEC; and
- Plastics and Resins.

In the subsequent paragraphs, we discuss what the likely impact on each segment will be on the basis of the structure of the segment, the sales growth pattern for new products in the segment, the product mix of the companies in the segment, and the likelihood that new chemicals in the segment would face restrictive action.

Surfactants

ICF found that the surfactant industry contains three different categories of producer: raw material suppliers, producers with large volume captive uses, and producers selling to others. The first two categories are dominated by large companies. Conoco, Monsanto, Union Carbide, Witco, Proctor & Gamble, Lever Brothers, Colgate-Palmolive, Shell Chemical, Rohm & Haas, GAF Corporation, and Borg-Warner are the major producers. The third category contains two large producers (Diamond Shamrock and ICI) and a host of producers that fall into the $10 to $200 million size category.[41] The industry experts believe that this segment is characterized by firms in all categories with the majority having total sales less than $3 million.

Direct out-of-pocket costs imposed by section 5 notice regulations may affect the surfactant industry. Most new chemicals in this segment involve marginal improvements on existing chemical products. This is an area of fairly active entrance and departure, and it is difficult to corner the market. It usually takes companies several years to recoup R&D costs.

Currently, most surfactants are derived from linear alkylbenzene sulfonates (LAS) which is not a completely biodegradeable structure and is banned in some areas. The industry is seeking a new process to replace LAS which is completely biodegradeable and is an equally effective compound. Environmental regulations of phosphate levels in water also affect the surfactant industry. Both of these regulations are well established and the surfactant industry has operated in a regulated environment for several years. Because the direction of regulation is clear, the surfactant industry is less likely to be affected by future regulatory action than the other innovative segments.

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[41] Meegan, Kline Guide, p. 166.

Catalysts

The catalyst industry includes approximately 10 industry giants as well as firms with operations less than $200 million.[42] Direct dollar out-of-pocket costs associated with section 5 notice regulations are not expected to pose a problem for this segment. Catalyst firms tend to introduce a few high volume products. Unlike most new chemical compounds, generally when a new, improved catalyst is discovered it will penetrate the market rapidly. A new and superior catalyst will command the market until a better catalyst is discovered.

Although direct costs should not pose a problem, uncertainty regarding trade secret disclosure is of great concern to the catalyst industry. Catalyst formulations are probably the most highly guarded trade secrets. Section 5 notice regulations could potentially disrupt this industry if information regarding new formulations were revealed as a result of the notice process.

Cyclic Intermediates

Cyclic intermediates are produced by firms in all sales categories above $3 million. The market structure varies depending on the specific chemical product. Fundamental, high volume compounds may have more than 10 major producers, whereas special low volume compounds usually have only one.[43]

Since new cyclic intermediate compounds differ only marginally from existing compounds, it may take several years for a new compound to gain a comfortable market share. As a result, direct out-of-pocket costs due to section 5 regulations will be important for this segment. Furthermore, the large number of firms in the $10 to $200 million category suggests that section 5 notice regulations may adversely affect the ability of these firms to gain the necessary market share required to recoup their initial investment.

Miscellaneous Synthetic Organic Chemicals, NEC

The miscellaneous synthetic organic chemical industry encompasses more than 1,000 firms, far more than any of the other innovative segments. Most of the firms in this segment have operations less than $10 million. Thus, section 5 notice regulations will most severely affect smaller firms through its impact on this segment. The extent of competition varies by chemical, and the leading manufacturer often differs from chemical to chemical.

Direct out-of-pocket costs imposed by section 5 notice regulations will be an important factor for this segment. The segment is extremely active,

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[42] Ibid., p. 147.

[43] U.S. International Trade Commission, Synthetic Organic Chemicals, 1977, (Washington, D.C.: Government Printing Office).

with a great deal of product entrance and departure. New products are usually distinguished by only marginal improvements over existing products. Thus, it is difficult to corner the market. It takes several years to recoup R&D costs, despite the fact that start-up costs tend to be low relative to other segments. Because of the diverse nature of this segment, more large volume products are introduced here than in other segments. The firms introducing these large volume products will be affected less by section 5 notice regulations than the other firms. Overall, small-volume producers in this segment will be significantly disadvantaged by the section 5 rules.

Industrial Inorganic Chemicals, NEC

The industrial inorganic chemical, NEC segment is diverse, much like the miscellaneous synthetic organic chemicals, NEC segment. Although not as large a segment as the miscellaneous synthetic organics, the industry structure is quite similar, with the majority of firms having operations of less than $10 million.[44] The extent of competition varies by chemical, as does the potential effect of section 5 notice regulations.

Direct and out-of-pocket costs imposed by regulations will be important factors for the segment. Most new chemicals in this segment involve marginal improvements to existing chemical products. This is an area of fairly active entrance and departure, and it is difficult for firms to corner the market. Firms require several years of sales to recoup R&D costs for a new product.

Rubber Processing Chemicals

The rubber processing chemical industry is fairly concentrated, with Goodyear, Goodrich, and Uniroyal responsible for approximately 50 percent of total production. Most firms have operations over $10 million. Some $3 to $10 million firms are active, but no entrepreneurs are found in this segment.[45] The advantage that generally results from a high degree of market concentration is minimized for the rubber processing chemical companies because their purchasers, synthetic rubber producers, are also highly concentrated.

Direct out-of-pocket costs imposed by section 5 notice regulations will affect the rubber processing industry but to a lesser degree than the miscellaneous synthetic organic chemicals, NEC segment, since fewer small firms produce rubber processing chemicals. Most new rubber processing chemicals are developed to satisfy a specific design feature that is desired by a rubber manufacturer. They are products that are marginal improvements on existing compounds. It takes several years for rubber processing chemical companies to recoup their R&D costs, and these products may have short lifespans.[46]

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[44] From meeting between ICF and industry experts, June 3, 1980.

[45] Meegan, Kline Guide.

[46] From meeting between ICF and industry experts, June 3, 1980.

Plasticizers

The plasticizer industry is very similar to the rubber processing industry, but it has more companies and is not as highly concentrated. It includes a few entrepreneurial firms, but the majority are spread evenly among the remaining categories.

Direct out-of-pocket costs may be a problem for this segment. Many small volume sales are involved, and new plasticizers tend to consist of marginal improvements on existing compounds to meet specific properties desired by plastics manufacturers.

Adhesives and Sealants

Adhesives and sealants is a diverse industry that includes firms in all sales categories but particularly those with $10 to $200 million operations.[47] New product development in this segment is oriented towards the introduction of many small volume chemicals. R&D is generally in response to a desire for an adhesive or sealant with slightly different properties than currently available, and so a new product is often similar to an existing chemical. Thus, the product may require several years to obtain a share of the market and to provide a return on the initial investment. This slow growth suggests that direct out-of-pocket costs imposed by section 5 notice regulations will influence the adhesive and sealant segment.

Plastic Materials and Resins

Basic plastic materials are produced in large volumes. As a result, the industry is dominated by large companies with entrepreneurial firms virtually eliminated from the market.

Direct out-of-pocket costs associated with section 5 notification requirements may be an important factor for the segment. Many small volume chemicals are constantly introduced as basic plastics are modified to meet the specific requirements of an endless array of applications. Since most new chemicals differ only marginally from existing compounds, it is difficult for them to capture a major market share.

SUMMARY

This examination of the nine innovative segments of the chemical industry has reemphasized the importance of the costs identified in Chapters 4 and 5.

Direct Out-of-Pocket Costs

Section 5 notice requirements will impose direct costs which will affect new product introduction in all innovative segments, except for the catalysts industry, because many small volume chemicals are involved which often provide only marginal improvements to existing chemicals and which require several years to recoup their R&D costs. New catalysts tend to be a few large volume chemicals with extremely rapid market penetration, thus direct out-of-pocket costs imposed by section 5 notice regulations should not adversely impact the catalyst industry.

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[47] Meegan, Kline Guide, p. 134.

Trade Secret Disclosure

Uncertainty and additional costs associated with possible trade secret disclosure could have a major impact on the catalyst industry, but does not appear to be a major problem for the other segments. Of course, small volume-small company producers may be tracked by large companies through the Federal Register which may lead to trade secret disclosure in all segments.

Delay in the Introduction of New Chemicals

Uncertainty and additional costs associated with delays in the introduction of new chemicals may have a slightly different effect on each innovative segment. Segments with a higher proportion of small firms--surfactants; miscellaneous synthetic organic chemicals, NEC; cyclic intermediates; and industrial inorganic chemicals, NEC--may have more difficulty bearing the additional costs resulting from delays in the introduction of a new chemical.

MACROECONOMIC EFFECTS

Macroeconomic effects of the section 5 notice regulations derive from the microeconomic effects discussed above. The manifestations of the effects will appear in changes in the rate of growth of the economy, changes in the industry concentration, and changes in the balance of trade. In the subsequent paragraphs, each of these is discussed.

Rate of Growth

The rate of growth of the economy will be affected by the segment changes analyzed above. The effects will be both short run and long run. The regulations will increase the economic costs of producing new chemicals. This will initially cause fewer new chemicals to be introduced into commerce, resulting in a potential for decreased growth.

To the extent that new chemicals increase efficiency and enhance productivity, the rate of growth of the economy initially will be further lessened by secondary impacts. It is highly probable that this will be the case because several of the affected segments (miscellaneous synthetic organic chemicals, NEC; industrial inorganic chemicals, NEC; catalysts; and cyclic intermediates) make products used in the manufacture of other products. Denied new, less costly raw materials, secondary products will not develop as rapidly as they have in the past.

Another way to understand the impact on the rate of growth of the economy is in terms of the theoretical models. Economic growth according to most theorists is a function of the level of investment. New chemical introductions result from investment in research and development activities. We can predict that the decreased investment connected with a drop in the rate of new chemical introductions will cause a drop in the rate of general economic growth.

In the longer run, it would be expected that the decreased number of new chemicals introduced will cause the relative costs of the factors of production in chemical-consuming industries to shift. In some cases the shift will be to non-chemical alternatives. It should be expected that this will spur investment in these industries which will offset to some extent the decreased investment in the chemical sector.

Because data do not allow for ex ante predictions about the number of new chemicals not introduced after the regulations become final, the short-run and long-run effects cannot be measured quantitatively.[48]

Industry Concentration

The second general area of effects will be in industry concentration. As we explained in Chapter 8 and earlier in this chapter, the affected segments will generally become more concentrated. Greater concentration will occur as regulation prevents the growth and perhaps even the viability of smaller firms.

As explained previously, those firms most affected by the rules will be those with less than $200 million annual sales. The higher costs of bringing a new chemical to market affect the entrepreneurs (the less than $3 million annual sales companies) in two ways. First, the direct and uncertainty costs associated with section 5 notices will cause some relatively small number of these firms to fail. Second, the recognition by the capital markets that section 5 rules reduce potential returns will result in less capital available to these companies. Nevertheless, because entrepreneurs typically are motivated by factors of which cost considerations are only a small part, it is doubtful that section 5 regulations will greatly reduce the level of entrepreneurial activity.

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[48] Some regulation experts today argue that the above logic is based on the false assumption that the rate of new chemical introductions will drop. They argue that the rate will not drop because companies will redirect their R&D to chemicals more likely to do less harm to the environment. Although ICF concurs that there will be this shift, ICF believes that these experts fail to recognize a critical fact--the new chemical that would have provided a lower cost, or more efficient input into the economy is an opportunity for economic growth foregone. Furthermore, at the present time the greatest magnitude of innovation occurs in those parts of the industry where the greatest reward can be obtained from innovation. Thus, even if the rate of new chemical introductions does not drop but shifts among kinds of chemicals, there will still be a lessening of economic growth due to these foregone opportunities.

For the $3 million to $200 million annual sales companies, the effects on industry concentration will be greater. Because these companies are more professionally managed than the entrepreneurs, they are more risk averse. Risk aversion implies the necessity to weigh uncertainties highly before committing funds to a project. These firms face greater uncertainty concerning the new regulations due to their lesser access to expertise about government regulations, and their product mix and research efforts usually are not very broad. We, therefore, can expect these firms to introduce fewer chemicals and thereby reduce their share of market in the future.

The recipients of this share of market will probably be the major chemical companies (the over $200 million annual sales). These firms have greater access to expertise about government regulation, broader (in terms of types of chemicals) research and development programs, and greater access to capital. Thus, they should prosper in comparison to their smaller competitors under the regulations.

Balance of Trade Effects

The effects of section 5 notice requirements on the U.S. balance of trade depends considerably on the relationship between the U.S. regulatory burden and the regulatory burden in other major chemical-producing countries. At one extreme, if the regulations applied to toxic chemicals in the United States are the same as in the other major-producing countries, one would expect no changes in the balance of trade in chemicals. If the regulatory burden were greater in the U.S., one would expect a shift in the balance of trade in chemicals away from the U.S.

Most foreign notification programs (with the exception of Japan) are pre-market rather than pre-manufacture programs. Further, notification under the European Directive is not due to take effect until March 1982. Nevertheless, in most cases, the information requirements are or will be similar. In fact, the testing requirements in foreign countries are much greater than in the U.S., so that useful information about new chemicals can be expected from the Foreign Manufacturers/Suppliers Form. On the other hand, small volume chemicals (under one ton annual production) do not require notification under EEC guidelines. (For further information see the importer contact issue paper.)

If the burden is greater in the U.S. (a questionable assumption at this time), some innovations which would have occurred in the U.S. will not. Sooner or later these innovations will occur in other countries and be adopted overseas. To the extent that use of these chemicals in other countries displaces imports from the U.S., the U.S. balance of trade in chemicals will suffer. In addition, imports of these chemicals into the U.S. may displace domestic production.

Although it is true that importers of new chemicals also face a U.S. regulatory burden, the burden per successful innovation will be less for imports than domestically produced chemicals. The reason for this is that notices must be filed for all new domestic chemicals including many which will ultimately be unsuccessful; but many of the unsuccessful chemicals developed abroad will have failed before any U.S. regulatory burden is imposed.

A precise quantitative estimate of the impact of notice requirements on the balance of trade cannot be made. Uncertainties about chemical regulations in other countries, not to mention uncertainties about the impact of section 5 on U.S. chemical innovation, would make any such estimate of little value.

CONCLUSION

ICF concludes from the foregoing analysis that the rate of introduction of new chemicals will decrease in the short-term because of the imposition of the section 5 notice. Much of the decrease will occur in the highly toxic chemicals of wide human and environmental exposure.

Some of the decrease will occur in other chemicals, however, not because EPA takes restrictive actions, but because of uncertainty. This uncertainty will stem from the very existence of TSCA, not just section 5. Chemical companies will not know and cannot be expected to know exactly how EPA will regulate chemical substances under section 5. Without extensive legal and government expertise -- something many chemical companies cannot afford -- uncertainty about EPA's actions concerning new chemicals will be a significant obstacle in the new chemical introduction process.

In an uncertain environment product managers act to minimize uncertainty. For many smaller chemical companies this could mean decreased R&D and decreased new chemical entity development. To the extent that these companies are in segments where new products are important for corporate survival, marginal small companies may be very vulnerable to failure. For other small companies this will mean a shift of R&D into what it perceives as being "safe" chemicals.

For larger companies the expected response will generally be a shift to "safe" chemicals. These companies, with their better access to information about EPA behavior, should be less uncertain than the smaller companies. However, until the EPA has developed a pattern of response to section 5 notices, these companies can be expected to behave much like their smaller competitors. Furthermore, the transition from R&D and new chemical development in the current fields to the "safe" fields will not be without cost.

As this report makes clear, the costs of the section 5 notice regulation are not quantitatively measurable. We have, instead, identified the most vulnerable segments, the kinds of costs they will experience, and the relation of these costs to alternative regulations under consideration. We have also discussed the ways in which chemical firms will be affected and the relative economic impact based on economic factors important to the success and failure of these firms. So, without quantifying, we have produced an economic impact analysis of the effects of section 5 notice costs.

PART II

ISSUE PAPERS

INTRODUCTION

EPA asked ICF to analyze their regulatory alternatives and the consequences of those alternatives for nine aspects of section 5 notice requirements. Those nine aspects are:

1. Confidentiality
2. Customer Contact
3. Definition of Importers
4. Importer Contact of Foreign Manufacturers/Suppliers
5. Exporters
6. Supplemental Reporting
7. Insufficient Submissions
8. Processor Reporting
9. Possession or Control

For each of these aspects, specific options available to EPA were provided. An evaluation framework was then developed to allow analysis of each option relative to other options. This evaluation framework was quantified where possible. Data for the analyses came from: public comments on EPA proposed section 5 notice requirements, hearing records, previous economic analyses, and ICF chemical segment analyses.

The analyses of these nine aspects of the section 5 notice requirements were used to generate the Comprehensive Program Options analysis in Chapter 5 of Part I of this report.

CHAPTER 1

CONFIDENTIALITY

Valid but conflicting interests surround the issue and treatment of confidentiality under section 5 notice information. On the one hand, industry's desire to maintain the confidentiality of business and trade secrets is based on the competitive advantage it derives from such secrecy. On the other hand, the free flow of information about chemicals should help obviate harmful exposures and possible abuses. To accommodate these interests, EPA must establish a mechanism to define a legitimate confidentiality claim.

The confidentiality provision of section 5 imposes some potentially heavy economic burdens on the chemical industry. The following discussion describes, first, the confidentiality options that EPA is now considering. These options have four elements:

- the method of asserting and substantiating confidentiality claims;
- the timing of substantiation;
- the requirements for generic masking; and
- the disclosure of chemical identity as part of a health and safety study.

A subsequent discussion analyzes the relative economic impact of the various options.

Finally, the objective of the confidentality policy and the specification of the options are studied.

SPECIFICATION OF EPA OPTIONS

EPA has specified a set of options for the several subissues which must be addressed in establishing an approach for the treatment of confidential business information. These alternatives are discussed in the following order:

- Assertion and Substantiation Options;
- Generic Masking Options; and
- Options for Disclosing Chemical Identity as Part of a Health and Safety Study.

Assertion and Substantiation Options

Four options for asserting and substantiating a claim of confidentiality were evaluated (see Exhibit 1-1). Each option includes:

- a method of asserting and substantiating a claim of confidentiality when the notice is submitted; and
- a time frame for substantiation.

There are three situations in which substantiation would be required:[1]

- when EPA receives a request under the Freedom of Information Act (FOIA) for information that has been claimed confidential;
- if EPA independently decides that it is "likely" that a request to disclose the information will "eventually" be received; and
- when EPA independently decides to determine if information is confidential, regardless of whether a request for the information has been received.

Option 1: No Substantiation with Submission. Items deemed to be confidential business information would have to be clearly designated either by a checkmark, red circle, or some other indicator of the submitter's choice. To substantiate the claim, the submitter would then respond to questions prepared by EPA and contained in a letter to the submitter. These questions would concern the nature and type of confidentiality claim.[2] Submittal of the notice and substantiation need not be concurrent.

Option 2: Some Substantiation with Submission. The January 10 proposal[3] requires that items asserted to be confidential be marked item-by-item. The same substantiation questions as Option 1 are required for the same areas of confidentiality. However, the timing of substantiation is different. Instead of substantiating everything at a later date, confidentiality assertions for both chemical identity and information in a health and safety study must be substantiated when the notice is submitted.

Option 3: Considerable Substantiation with Submission. This option is really option 2 with the additional requirement that use data which is claimed to be confidential must also be substantiated when the notice is submitted.

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[1] These situations are specified in EPA regulations, 40 CFR Section 2-204(a).

[2] These categories and the number of questions under each are: chemical identity (nine questions); other information in health and safety study (eleven questions); manufacturer's identity (four questions); production volume (six questions); use data (nine questions); physical and chemical data (thirteen questions); and miscellaneous (eight questions).

[3] The proposal is at 44 Federal Register 2242, et seq.

EXHIBIT 1-1

ASSERTING AND SUBSTANTIATING

	Option 1 No Substantiation With Submission	Option 2 Some Substantiation With Submission	Option 3 Considerable Substantiation With Submission	Option 4 Complete Substantiation With Submission
Assertion Method	● Assertion	● Assertion - Item-by-Item	● Assertion - Item-by-Item	● Assertion - Linkage and Categories
When	- Not EPA prescribed ● Substantiation only upon EPA request	● Substantiation with submission - Chem ID - H&SS data ● Remaining confidentiality claims substantiated upon EPA request	● Substantiation with submission - Chem ID - H&SS data - Categories of use ● Remaining confidentiality claims substantiated upon request	● All Confidentiality claims substantiated with submission
Method of Substantiation	Series of questions	Series of questions	Series of questions	Limited questions

This procedure would let EPA know whether or not the information could be published in the section 5(d)(2) notice.

Option 4: Complete Substantiation with Submission.[4] A claim of confidentiality is asserted by categorizing information under one of seven general groupings:

- Category A: Manufacturer's Identity;
- Category B: Specific Chemical Identity:
- Category C: Production Volume;
- Category D: Use Data;
- Category E: Process Information;
- Category M: Proportions of a Mixture (only for use in health and safety study); and
- Category F: Other Information.

Boxes are provided beside each item of information, and the appropriate letters are placed in the box to indicate the confidentiality category in which the information falls. Some information is automatically "linked" to or included in a category, and nothing needs to be done beyond indicating that the information is claimed confidential.[5] For other information, the "linkage" is not automatic and must be established by explaining how disclosure of the information would reveal confidential information about the particular category.

Substantiation of the confidentiality claims occurs as follows:[6]

- There is a confidentiality certification which is to be signed by the appropriate individual. This individual certifies that:
  - -- The submitter has taken and will continue to take measures to protect the confidentiality of the information;

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[4] The reproposal is at 44 Federal Register 59764 et seq.

[5] All items which are automatically linked can be claimed confidential by checking only one box--i.e., the claim does not have to be asserted individually for each item of information.

[6] The list of substantiation questions under this option is in a latter section of this report.

  - The information claimed confidential has generally not been "reasonably obtainable" by outsiders;

  - The information is not publicly available elsewhere; and

  - Disclosure would cause "substantial harm" to the submitter's competitive position.

- Manufacturer's identity is substantiated by signing the certification statement. There are no other questions to be answered.

- Specific chemical identity is substantiated by answering a series of eight questions.

- For production volume, use data, process information, and proportions of a mixture, one substantiation question must be answered if manufacturer's identity has been claimed confidential and the submitter is asserting additional confidentiality claims. For example, the submitter must explain why and how disclosure of the particular information would hurt its competitive position. The same procedure is followed when chemical identity has been claimed confidential. If neither manufacturer's identity nor chemical identity has been claimed confidential, and the submitter asserts additional confidentiality claims, no substantiation questions need be answered for the four categories mentioned above.

- For information which does not fall into one of the six specific categories, the submitter must answer a series of six questions to substantiate the confidentiality assertion.

The substantiation questions must be answered only once, regardless of how many times information is claimed confidential under a particular category, except for "other information." For that category, the six questions must be answered each time information is claimed. All substantiation must be submitted with the notice.

Generic Masking Options

The second sub-issue of confidentiality is the development of generic information. In some instances when asserting confidentiality, the submitter would be required to propose a generic name or generic information to replace the confidential information. The three options for substantiating generic information differ in the amount of generic information they require as shown in Exhibit 1-2.

Option 1: Some Generic Information. The January 10 proposal required the submitter to provide some generic information:

- If chemical identity is claimed confidential, a generic name must be provided. The submitter is encouraged to seek prior EPA approval of the generic name before submitting it. The generic name is to be "only as generic as necessary" to protect the confidential chemical identity, and "should reveal to the maximum extent possible toxicologically significant aspects of the molecular structure". The submitter also is encouraged to explain why additional specificity would reveal confidential business information. An appendix to the January 10 proposal gives guidance for creating the generic name. It is possible that the submitter will have to develop more than one generic name before obtaining EPA approval.

- If use data is claimed confidential, the submitter is required to provide a generic use description supplemented with the likely exposures to humans or to the environment.

Option 2: Considerable Generic Information. This option has a generic scheme encompassing four classes of information:

- If chemical identity is claimed confidential, the submitter is to provide EPA with three generic names if a prior agreement (arrived at during pre-notice communication) has not been made with EPA regarding an appropriate generic substitution.[7]

- If use data is claimed confidential, the submitter is expected to provide a generic use descriptors developed in accordance with a scheme in which the submitter picks a discriptor generic in each of six categories of use characteristics.

  -- degree of containment;
  -- level of environmental release;
  -- type of population exposed;
  -- type of environmental release;
  -- type of human contact; and
  -- average frequency of human contact.

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[7] These names are to be developed in accordance with the instructions in Appendix II of the January 10 proposal. If none of the three names are satisfactory to EPA, EPA will propose a generic name. If EPA's generic name is not satisfactory to the submitter, the submitter will submit a fourth generic name and explain why EPA's candidate would reveal CBI. If the submitter's fourth term is unacceptable, EPA will publish its choice.

If the submitter does not use this scheme, it must explain why use of the scheme would reveal CBI and provide an alternative generic name. If the submitter fails to provide a generic name, or provides a generic name that is too generic, EPA will develop and disclose generic information.

- If disclosure of the physical and chemical properties of the new chemical substance would reveal CBI, the submitter can use EPA-supplied ranges to report the value of these properties. The ranges are provided for five properties:

  - vapor pressure;
  - density;
  - solubility;
  - melting point; and
  - boiling point/sublimation point.

  If the ranges supplied by EPA are not used, the submitter must explain why ranges would reveal CBI. The submitter would have to provide alternative generic information for these properties. If other chemical and physical properties are claimed confidential, submitters would supply their own ranges.

- If manufacturer's identity is claimed confidential, the submitter must provide a generic description incorporating three categories of characteristics:

  - general geographic location of the company;
  - size of the company, in total annual sales; and
  - type of company by Standard Industrial Classification Code (three-digit).

  EPA has provided a list of these characteristics. If the three-digit SIC reveals the manufacturer's identity when combined with its two other characteristics, the submitter may provide the two-digit SIC with an explanation of why the three-digit code is too specific.

For any of these generic requirements, the submitter may explain why the generic information cannot be developed. EPA will decide whether this is sufficient justification for not providing generic information.

Option 3: No Generic Information. A final alternative is to not require generic information. When information is confidential, no generic information would be provided to the public.

Options for Disclosing Chemical Identity as Part of a Health and Safety Study

If a health and safety study is submitted two subissues must be decided:

- when the chemical identity will be disclosed; and
- how the chemical identity should be added to the inventory.

Timing Options. Disclosure of chemical identity, as a concomittant of a health and safety study, might take place at any of the following moments:

- when the notice is submitted;
- when manufacture begins; and
- when the new chemical substance is distributed in commerce.

Inventory Options

There are two forms in which the chemical identity can be added to the inventory:

- by generic name; or
- by specific chemical name.

EXHIBIT 1-2

GENERIC OPTIONS

Option 1 Some generic Information	Option 2 Considerable Generic Information	Option 3 No Generic Information
• Provide generic information for: (1) Chem. ID (2) Chem Use	• Provide generic information for: (1) Chem. ID (2) Chem Use (3) Manf. ID (4) Chem & Phy. Properties	• No generic information must be submitted

ANALYSIS OF ISSUES

This section analyzes the issues in terms of the costs they impose on the the submitter of the notice. A general dicussion of the kinds of costs involved precedes the analysis of how costs vary by option. The costs attributed to the various options were derived from sources including industry comments on the proposal and reproposal, EPA comments on the proposal and reproposal, and ADL estimates derived for the reproposal.[8]

Kinds of Costs

Exhibit 1-3 lists the three of kinds of costs that are imposed directly on submitters. In the subsequent paragraphs each is addressed.

EXHIBIT 1-3

CONFIDENTIALITY COSTS

Submitter:	Cost 1.	Disclosure of trade secrets due to the amount and nature of notice information made public.
	Cost 2.	Out of pocket expenditures due to procedural and administrative requirements.
	Cost 3.	Uncertainty about what kinds of information EPA will require and how much of that information might be disclosed.

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[8] Comments of the Manufacturing Chemists Association on EPA Proposed Regulations for Premanufacture Notification Under Section 5 of TSCA (hereafter: MCA proposal comments. Note: MCA subsequently become CMA), March 26, 1979; Comments of the Chemical Manufacturers Association on EPA's Reproposal of Forms and Rules for the Submission of Premanufacture Notices Under Section 5 of the Toxic Substances Control Act (hereafter: CMA reproposal comments), November 30, 1979; Other industry comments including those of the Synthetic Organic Chemical Specialities Manufacturers Association (CSMA); Comments by Environment Defense Fund (EDF), Environmental Action, and National Resources Defense Council (NRDC); EPA's Interim Policy (44 Federal Register 28564-28572); EPA's Reproposal (44 Federal Register 59764-59783); Industry Interviews by Arthur D. Little (ADL Interviews); and Arthur D. Little, Inc., Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, (Cambridge, Mass.: Arthur D. Little, September 1979)--hereafter, ADL Study.

Cost 1: Disclosure of Trade Secrets. The confidentiality policy will affect the probability of disclosing trade secrets. Trade secrets are a very important factor in the chemical industry and are sometimes critical to the new chemical introduction process. This is particularly true as the demand for many chemicals is very price-elastic. Because a multitude of substitutes may exist, there may be little difference between the successful new chemical and the new chemical which fails. Every competitive advantage, therefore, becomes significant to the individual firm. The existence of a trade secret in an individual firm is a source of competitive advantage.

Trade secrets are not limited only to the chemical identity of a new chemical. The process by which an intermediate chemical is manufactured could be far more significant than its identity. A manufacturer's identity and location may reveal information about the potential market for the new chemical to a critical competitor. Therefore, the information required in the notice may include items that the submitter would not otherwise reveal.

The distinction between what will and will not lead to the disclosure (if not directly, then indirectly) of CBI may frequently be a point of contention between EPA and the submitter; the cost of potentially reduced or destroyed competitive advantage must be included in the evaluation of confidentiality issues and options.

Cost 2: Out of Pocket Expenditures. These are the procedural or administrative costs which the submitter must absorb in complying with the confidentiality requirements of section 5. The largest component is the personnel required to complete forms (i.e., answering the substantiation questions) and to furnish information (i.e., generic information) required by EPA's confidentiality procedures. These costs include the actual time required to fill out the forms (i.e., the purely procedural tasks), time spent in consultation with EPA representatives, and time spent on internal consultation.

Cost 3: Uncertainty About EPA Decisions. The submitter cannot ignore the potentially adverse situations which may arise from an unfavorable (in the submitter's view) determination by EPA concerning the confidentiality claims asserted. Therefore, preparations may have to be made for each such situation or at least for the most likely situations. Such preparations divert some of the submitter's resources that could be used for other purposes if this contingency planning or preparation were not required.

Cost Associated with Options on How to Assert and Substantiate

Previously, we identified the four options under consideration for asserting and substantiating confidentiality claims. The four options represented combinations of two sub-issues: (1) method and (2) timing. First we discuss the relative costs of the two "method" options. They are summarized in Exhibit 1-4, following the discussion below.

Specification of Options

The two options EPA could use as the basis for its assertion and substantiation requirements were mentioned previously as being "item-by-item" or "categories and linkages." They are discussed in greater detail here.

Option 1. Assert item by item and substantiate by responding to a series of questions. The assertion is straightforward; it probably would require that the submitter check a box (printed on the PMN form) beside information that is claimed to be confidential and mark clearly any confidential material contained in the notice as an attachment. The series of substantiation questions would either be a part of the form (or the instructions for such a form) or would be in a form letter addressed to the submitter. How the questions are presented depends upon the timing of substantiation.

Option 2. Assert by categories and linkages; substantiate by making a general certification (which would cover manufacturer's identity),[9] answering a series of questions for specific chemical identity and "other" information and answering no more than two questions each for use data, process, mixture, and production information.[10]

Relative Costs of Options 1 and 2

The relative costs of these two options are discussed below. Exhibit 1-4 summarizes these costs.

Both options entail similar probabilities of disclosing the submitter's trade secrets. Under option 2 the submitter may feel that it is incurring a higher risk of revealing CBI because it has to provide information about the linkage of CBI to specific categories as well as substantiate its claim of confidentiality for that information. In fact, the two options do not require the submission of significantly different information and do not involve costs that can be attributed to either option. All material, including substantiation and linkage material, submitted under either option is afforded the same protection if CBI is involved.[11]

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[9] This certification would also cover confidentiality claims for use data, production volume, and process information if neither manufacturer's identity nor chemical identity have been claimed confidential.

[10] These questions must be answered only if manufacturer's identity or chemical identity is claimed and held confidential.

Each option presents different administrative requirements for the submitter which in total are similar.[12] The substance of what the submitter is required to submit to EPA does not differ significantly between the two options. However, option 2 imposes greater assertion requirements and lesser substantiation requirements. The assertion requirements are greater because the linkage and category approach requires more attention and effort than the item-by-item checkoff. However, the magnitude of the burden is minimized because the linkage questions only require a narrative explanation of how disclosure of the information would reveal confidential information about a particular category.[13] Industry comments have indicated a preference for narrative responses instead of specific responses to a series of questions.[14] The substantiation requirements are significantly less for option 2 than option 1[15] because option 2 has only two long series of questions (for specific chemical identity and for "other" information) instead of several series associated with option 1; four categories have no more than two questions to be answered, and manufacturer's identity does not involve any substantiation questions. Thus, the additional burden of asserting a confidentiality claim under option 2 is counterbalanced by the reduced burden of substantiating the claim under option 2.

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[11] EPA has indicated that the substantiation itself, can be claimed confidential. (Interim Policy 44 Federal Register 28568, May 15, 1979). Industry's concern is that adequate protection is not provided for the linkage and substantiation material. (See CMA reproposal comments, pp. 119-120, 170. At p. 119, another threat to CBI is suggested: ". . . the question format proposed by EPA will be burdensome for submitters, and its complexity and attendant expense may deter companies from asserting legitimate trade secret claims." Failure to assert legitimate trade secret claims may be due to factors other than just substantiation requirements. Because this failure cannot be isolated as due solely to TSCA regulations, it is not included as a cost in the discussion.)

[12] In the ADL study, the range of time (in essence, the out-of-pocket cost) required for asserting confidentiality under the reproposal was estimated to be 2 to 24 hours (p. 52) and the range for developing the linkage and substantiation material was estimated to be 12 to 100 hours (p. 52). The study also noted that, in comparing the proposal's and reproposal's substantiation requirements, it was "reasonable to assume that greater company-by-company variations in effort expended on the second step in the confidentiality process--developing substantiations--would occur in the absence of EPA's current (i.e., the reproposal) confidentiality provisions. Under these conditions, the range of time required could conceivably be much broader than the range estimated above." (p. 51, note). The wider range would exist because the submitter's assertion and substantiation under the proposal would be less structured than under the reproposal.

[13] Industry has claimed that the linkage system is "complex and confusing" and that it "will require a considerable expenditure of time and effort by PMN submitters. . . ." CMA reproposal comments, p. 99. The industry also has indicated a preference for the proposal's checkoff method of assertion (MCA (subsequently CMA) comments on the proposal, p. 299; and CMA comments on the reproposal, p. 101). The ADL study estimated that actual form preparation would take two to 16 hours, and review of the completed form would take two to 20 hours. The total time required by the reproposal's confidentiality process was estimated to be 18 to 160 hours (p. 52). No time estimates were made based on the proposal's requirements.

Although the substance requirements are similar, option 2 may involve greater out of pocket costs. There are two reasons for these increased costs:

- Option 2 requires that the submitter explain its confidentiality claims by providing information with two different orientations--establishing links between information and confidentiality categories and substantiating confidentiality claims. The submitter's efforts to provide these two different kinds of information may be sufficiently different to require greater out of pocket expenses than option 1.
- The assertion requirement of option 2 that the linkage to a confidential category be shown must be satisfied each time confidentiality is claimed for information not automatically linked to a category. If there is a large quantity of non-automatically linked information, the assertion burden could become quite significant.[16]

The submitter's uncertainty is relatively greater under option 1. Option 2 explicitly requires the submitter to demonstrate that information claimed confidential is related to the category under which the claim is made.[17] This requirement, which clearly identifies the basis for EPA's assessment of the validity of a confidentiality claim, enables the submitter to address those points directly relevant to EPA's determination. Option 1, while requiring the submitter to provide the same general substantive material as option 2, does not directly link claims to that information which is most relevant to EPA's consideration of confidentiality claims. Therefore, under option 2 the submitter may have less uncertainty as to whether or not its claim will address points relevant to EPA's consideration of a confidentiality claim.

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[14] CMA comments on the reproposal, p. 103.

[15] EPA indicated (p. 59774, reproposal) one reason for limiting to two the number of substantiation questions for categories of information was "to lessen the need for multiple confidentiality claims."

[16] The timing of substantiation has a bearing on the administrative or out-of-pocket costs. This is discussed in the section "When to Substantiate".

[17] Although the industry has indicated that it considers this approach "complex and confusing" (CMA reproposal comments, p. 99), EPA considers the approach to be a clarification of what the Agency needs to make a decision about confidentiality (EPA comments on the reproposal, 44 Federal Register 59774-59775).

EXHIBIT 1-4

THE RELATIVE COSTS OF OPTIONS FOR ASSERTING AND SUBSTANTIATING CONFIDENTIALITY

	Option 1 (Check-off/Series of Questions)	Option 2 (Linkage/Reproposal Questions)
Submitter Cost 1 ((P) disclose trade secret)	1	1
Submitter Cost 2 (Out of pocket costs)	1	1
Submitter Cost 3 (Uncertainty)	2	1

The option with the higher number (i.e., 2) has the higher relative cost. Where there are no significant differences in the costs imposed by the options, they are equally ranked.

Source: MCA (subsequently CMA) proposal comments; CMA reproposal comments; ADL Study; EPA reproposal comments.

WHEN TO SUBSTANTIATE

The cost associated with the requirement of submitters to substantiate presents clearly defined alternatives with well-defined costs. The four options are discussed at length and their relative costs are summarized in Exhibit 1-5, following the discussions on specification and relative costs.

Specification of Options

There are four timing options that are presented for analysis.

Option 1 requires substantiation only upon request from EPA. The submitter could assert confidentiality without substantiating the assertion until requested.[18]

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[18] EPA's general confidentiality regulations define three such situations. See footnote 2, *supra*, and accompanying text.

Option 2 requests that confidentiality claims for chemical identity and health and safety study data be substantiated when the notice is submitted; all other information is substantiated (e.g., manufacturer's identity, use data, production volume) upon request.

Option 3 requires that substantiation for the minimum amount of material be included in a section 5(d)(2) notice (i.e., substantiate confidentiality claims for specific chemical identity, use data, and information in a health and safety study); to be submitted when the notice is submitted; all other information (i.e., manufacturer's identity, production volume, physical and chemical properties data, and other information) is to be submitted upon request.

Option 4 requires substantiation for all confidentiality claims to be submitted with the notice. The rationale for this option is that information should be made available as soon as possible. Thus, instead of waiting for an FOIA request, confidentiality would be determined when the notice is received, and everything determined not to be confidential would be publicly disclosed (either through publication or by being placed in the public file).

Relative Costs of the Options

The relative costs of these four options are discussed below. Exhibit 1-5 summarizes these costs.

The cost to the submitter in terms of the probability that trade secrets will be disclosed is minimized by option 1 and maximized by option 4. Although protection is available for substantiation which is itself CBI, mistaken disclosure is still a possibility. The harm posed by this situation (i.e., the damage if such an event occurred multiplied by the probability of its occurrence) is not likely to be great, but it increases as EPA is given more confidential information in support of the claims. Therefore, when substantiation is provided only upon request, less information is in EPA's possession and less probability exists for disclosure of CBI. Since option 1 represents the situation where the least amount of information is initially provided to EPA, it is the least expensive to the submitter in terms of probable disclosure of CBI. Application of this analysis indicates that option 4, which supplies EPA with the most information initially, is the most costly of the four options. In the long run, if information claimed confidential in a notice is subject to many requests for disclosure, it may be that more information will have to be submitted to EPA under those options which require less substantiation initially.19/ However, since the latter situation is speculative and the former (i.e., what is required to be substantiated when the notice is submitted) is certain, option 1 is least costly, and options 2, 3, and 4 represent successively higher costs.

19/This is possible because piecemeal substantiation can be item-specific, while substantiation submitted with the notice is intended to cover all claims under a particular confidentiality category.

other three options) the submitter's initial administrative burden in providing EPA with the notice. These initial relative costs are certain, since the notice must be submitted to EPA. Any subsequent relative costs, however, may be quite different.

If there are many requests for substantiation after the notice is submitted under option 1, the submitter would have to return to the substantiation question in a piecemeal fashion. Substantiating a claim piece-meal fashion after satisfying most of the notice requirements would be less efficient than submitting substantiation along with the notice. The loss of efficiency occurs because the submitter must refamiliarize itself with the relevant factors in the notice and because some duplication of administrative effort will be necessary. In this situation, it is not clear that one option would keep administrative costs lower than the other three options.[21] Therefore, balancing the certain relative administrative costs of providing substantiation with the notice against the uncertain relative administrative costs of providing substantiation upon request, leads us to conclude that option 1 is the least costly in terms of the submitter's administrative burden, and options 2, 3, and 4 represent successively higher costs.

The costs imposed by the submitter's uncertainty are increased by Option 1 and decreased by Option 4. The submitter's uncertainty in this context is derived from two sources. First, if substantiation is not provided with the notice, the submitter does not know when (or if) subsequent substantiation will be required; therefore, the submitter does not know whether its claims of confidentiality (for which no substantiation has been submitted) will be challenged. Second, when less than all the confidentiality claims are substantiated, the submitter may not fully realize the inter-relation of the confidentiality claims[22] and may either claim too much confidential (which would result in unnecessary administrative expenses) or not claim enough confidential (which could lead to unnecessary disclosure of CBI). As more confidentiality claims are substantiated coincidentally, these uncertainty costs would be lessened. Therefore, option 1 represents the greatest uncertainty costs, and options 2, 3, and 4 represent successively lower uncertainty costs.

GENERIC INFORMATION

By supplying generic information, submitters are trying to protect trade secrets while allowing EPA to disseminate to the public information about new chemicals introduced into the commercial market. The less generic the information, the less protection the submitter has for its trade secrets. Yet, the more generic the information, the less use such information has for public evaluation of a new chemical substance. EPA has suggested that generic information can be specific enough to give meaningful information to the public, yet broad enough to protect the submitter's confidential interest in the specific information behind the generic mask (see, for example, 44 Federal Register 59777). The relative costs of the three options are summarized in Exhibit 1-6, following the discussion below.

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[21] This would depend on the volume of subsequent requests and the efficiency difference between substantiating when other notice requirements are being met, and substantiating after the notice has been submitted. The volume of requests for disclosure has been the subject of some experience under the current interim policy.

[22] See 44 Federal Register 59775.

Specification of Options

There are three generic options described below.

Option 1 requires generic information that is only used to determine chemical identity and categories of use. Only one generic name for chemical identity must be submitted, and the submitter is encouraged to obtain EPA approval before submission. The rule is that the generic name is to be "only as generic as necessary to protect the confidential identity of the particular chemical substance". The generic description for categories of use must be supplemented by the likely exposures to humans or to the environment and toxicologically significant information.

Option 2 requires the submitter to provide generic information for chemical identity, categories of use, manufacturer's identity, and physical and chemical properties. For chemical identity, the submitter must initially provide EPA with three generic names.[23]

Option 3 requires no generic information to be submitted. If an item of information was confidential, nothing would be made public.

Relative Costs of the Options

The three options present a spectrum of options with well-defined costs.

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[23] This procedure can be avoided if the submitter opts to obtain EPA approval of a generic name prior to submission of the notice.

EXHIBIT 1-6

RELATIVE COSTS OF OPTIONS FOR GENERIC MASKING

	Option 1 (chemical ID and chemical use)	Option 2 (chemical ID, chemical use, manufacturer's ID, and physical/ chemical properties)	Option 3 (no generic information)
Submitter Cost 1 ((P) disclose trade secret)	2	3	1
Submitter Cost 2 (Out of pocket costs)	2	3	1
Submitter Cost 3[a] (Uncertainty)	2	3	1

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[a] The option with the highest number (i.e., 3) has the highest relative cost.

Source: CMA reproposal comments, MCA (subsequently CMA) proposal comments, CSMA comments, SOCMA comments, comments by Monsanto and FMC Corp. EDF comments, EPA reproposal comments.

Option 3 imposes the lowest relative cost in terms of the probability that the submitter's trade secrets will be disclosed.[24] Option 3 requires the least amount of information from the submitter for public disclosure. As a general rule, the probability of trade secret disclosure has a direct relation to the amount of information which is publicly disclosed. Since option 3 requires no generic information, it imposes the least amount of costs in these terms; options 1 and 2 are relatively more costly. Option 1, however, requires only two items of generic information while option 2 requires four. In addition, option 1 enables the submitter to develop the generic categories of use information according to its own scheme which is responsive to the submitter's concerns about trade secret disclosure. Option 2 provides the same opportunity, but requires an additional explanation of why EPA's scheme is not adequate (providing such an explanation would also involve additional administrative costs for the submitter). Under both options 1 and 2, there is a possibility that the initial section 5(d)(2) notice (published 5 days after receipt of the notice) will have to be amended if its generic chemical identity is determined to be too broad. Combining the initial generic name published and the amended version of the generic name may reveal sufficient information to unmask the specific chemical identity. Of the three options, therefore, option 3 imposes the least relative costs, and options 1 and 2 impose successively higher relative costs in terms of the probability that trade secrets will be disclosed. (See also, MCA (subsequently CMA) comments on the proposal, p. 319.)

Option 3 involves the lowest relative costs for the submitter in terms of out-of-pocket expenses. Because option 3 requires the submitter to develop and submit no generic information, it represents a clearly lower relative out-of-pocket cost. Another savings is the absence of negotiations with EPA concerning the adequacy of particular generic information.[25] It is more difficult to determine which of the other two options is least costly, because the two are not directly comparable. In particular, option 2 permits three of the four generic descriptions to be constructed from a "laundry list" of characteristics or ranges compiled by EPA -- a process far easier than developing generic information "from the ground up" as required by option 1. However, option 2 also gives submitters the alternative of using their own schemes (with proper justification) to develop this same information. The submitter will use the EPA scheme only if it believes the results will be satisfactory from its viewpoint. The relative costs of the two options will depend upon its decision.

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[24] Industry has made clear its position that supplying any generic information for public disclosure will compromise the submitter's confidential business information. The following examples from CMA's comments on the reproposal indicate industry's attitude:

- It is a faulty premise "that useful generic data can be disclosed to the public without itself revealing the underlying confidential information." (p. 151).
- "The purported benefit of the (generic) scheme . . . is highly dubious and in any event cannot be achieved without a serious risk of compromising submitter's rights to confidentiality." (p. 156).
- "Although disclosure of these range data would be of questionable value to the public, they may prove extremely valuable to the submitter's competitors." (p. 161).

[25] See CMA's commments on the reproposal, pp. 104, 151, and 155.

Unlike option 2, option 1 does not require submission of generic information for manufacturer's identity or physical and chemical properties; this represents a clear time savings for option 1 in comparison to option 2. Option 1's provision for generic categories of use information, however, requires development solely by the submitter, and thus seems more burdensome than option 2's "laundry list" alternative. (Note: if the submitter opts for its own scheme for developing the generic categories of use information, there is little difference between options 1 and 2 on this point.) Similarly, neither of the two option's requirements for generic chemical identity presents clear-cut administrative cost savings over the other option. Option 1 requires the submission of only one generic chemical identity, but obtaining EPA's prior approval of the choice is encouraged. Thus, the submitter is not formally limited in the number of generic names it may have to develop. Option 2 requires the submitter to develop at least 3, but no more than four generic chemical identities. Under option 2, the submitter also has the alternative of obtaining EPA's prior approval for a single generic chemical identity and avoiding the requirement for initial submission of three generic names (under this alternative, option 2 is identical to option 1).

In sum, option 1 requires less information than option 2; where the two options overlap (i.e., for chemical identity and categories of use), it is not clear which one will, in practice, require more time of the submitter. By requiring less information, option 1 appears to require less time than option 2 and should represent a relatively lower out-of-pocket cost for the submitter.26/ Therefore, option 3 is the least costly option in terms of the submitter's out-of-pocket costs, and option 2 is the most costly.

Option 3 imposes the least costs in terms of submitter uncertainty about EPA actions. EPA decides whether generic information is adequate (i.e.,

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26/It should be noted that option 2 presents a situation in which the submitter may opt for higher costs of one kind in order to avoid higher costs of another kind. In particular, the EPA-supplied scheme for chemical use, manufacturer's identity, and physical and chemical properties may represent time cost savings because the submitter does not have to design its own framework. However, in the submitter's opinion, the EPA scheme may not provide as much protection for trade secrets as a generic description developed independently by the submitter. Although it would involve higher administrative costs to develop the independent description, the submitter may choose to incur that cost in order to avoid the much greater cost imposed by endangering the confidentiality of trade secrets.

whether it is as specific as possible without revealing CBI). The submitter, therefore, may be uncertain whether its perception of what is adequate coincides with EPA's perception. Since option 3 involves no submission of generic information, the question of EPA's acceptance of the information does not arise. Option 1 involves only two kinds of generic information, while option 2 involves four; option 1, therefore, should involve less uncertainty for the submitter relative to option 2.[27] Option 2, however, does lessen substantially the costs associated with uncertainty due to the requirement for additional generic information. Under option 2, EPA has provided a framework for developing all four items of generic information and has indicated that if this framework is used, the information developed will generally be acceptable to EPA.

CHEMICAL IDENTITY AS PART OF HEALTH AND SAFETY STUDY

This issue is one of particular sensitivity to submitters. Two sets of options are discussed; the first is the timing of disclosure for chemical identity that is part of a health and safety study,[28] and the second is how chemical identity will be added to the inventory. The relative costs of the two sets of options are summarized in Exhibits 1-7 and 1-8 below.

Chemical Identity Disclosure Timing Options

If a notice includes chemical identity which will be disclosed because of the factors discussed above, EPA has three options on when to disclose this information.

Option 1 requires disclosure of the chemical identity when the notice is submitted. Thus, the specific chemical identity will be known at least 90 (and as many as 180) days before the submitter can begin its commercial manufacture.

Option 2 requires disclosure when manufacture begins which prevents disclosure during the period between submission of the notice, its approval, and the commencement of manufacture.

Option 3 requires disclosure when the chemical is distributed in commerce. Distribution occurs some time after manufacture begins, but it is not apparent that this is a significant difference from option 2. The submitter will not be commercially manufacturing the chemical without

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[27] Under both options 1 and 2 the submitter can seek pre-notice consultation with EPA. This reduces uncertainty about whether the generic information submitted with the notice will be adequate. However, there still is uncertainty during the pre-submission stage, and this uncertainty also is relatively higher for option 2 than for option 1.

[28] If chemical identity is not a part of the health and safety study, the issue does not arise.

EXHIBIT 1-7

THE RELATIVE COSTS OF OPTIONS FOR TIMING THE DISCLOSURE OF CHEMICAL IDENTITY AS PART OF A HEALTH AND SAFETY STUDY

	Option 1 (disclose when PMN submitted)	Option 2 (disclose when manufacture begins)	Option 3 (disclose when distributed in commerce)
Submitter Cost 1 ((P) disclose trade secret)	3	2	1
Submitter Cost 2 (Out-of-pocket cost)	1	1	1
Submitter Cost 3 (Uncertainty)	1	1	1

A "1" indicates the least costly alternative. Where there are no significant differences in the costs imposed by the options, they are equally ranked.

Source: MCA (subsequently CMA) proposal comments; Environmental Action comments; EDF comments; NRDC comments; CMA reproposal comments; EPA comments accompanying the Interim Policy and the Reproposal.

EXHIBIT 1-8

THE RELATIVE COSTS OF OPTIONS FOR PLACING CHEMICAL IDENTITY (CONTAINED IN A HEALTH AND SAFETY STUDY) ON THE INVENTORY

	Option 1 (Place on inventory by specific name)	Option 2 (Place on inventory by generic name)
Submitter Cost 1 ((P) disclose trade secret)	2	1
Submitter Cost 2 (Out-of-pocket cost)	1	1
Submitter Cost 3 (Uncertainty)	1	1

A "1" indicates the least costly alternative. Where there are no significant differences in the costs imposed by the options, they are equally ranked.

assurances that it has a market for the chemical. Thus, if the manufacturing process is relatively short, it may be a matter of weeks between the commencement of manufacture and the distribution in commerce. On the other hand, if the manufacturing and distribution process is relatively lengthy, there may be a significant time difference between the commencement of manufacture and the distribution in commerce.

The Relative Costs of the Timing Options

Each of these options imposes different costs on the submitter. Exhibit 1-8 summarizes the relative costs.

Option 1 provides the earliest disclosure. The earlier disclosure imposes a great burden on the submitter because its specific chemical identity is revealed before commercial manufacture has begun.[29] Earlier disclosure increases the submitter's costs of maintaining trade secrets. For example, if a trade secret's primary importance lies in giving the submitter an early start on its competition, the earlier the trade secret (in this instance, the chemical identity) is disclosed, the greater the harm. Other costs for the submitters are not significantly affected by this set of options.

Option 2 is the mid-ground of the three options. Information is revealed more slowly than option 1, but more quickly than option 3. Similarly, option 2 prevents possible disclosure of trade secrets for a longer period than does option 1, but not as long as option 3 (although, as discussed above, the length of the interim between 2 and 3 is not clear).

Option 3 imposes the lowest costs for submitters. Option 3 protects the chemical identity from disclosure longer than the other two options and, thus, postpones possible trade secret disclosure. Furthermore, option 3 may provide the submitter with all the competitive advantage it had initially planned.

Inventory Options

The final set of options is the addition of chemical identity (that is disclosed as part of a health and safety study) on the inventory. There are two options:

- addition to the inventory by specific chemical name, or
- addition to the inventory by generic chemical name.

Exhibit 1-9 summarizes the relative costs.

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[29] The industry repeatedly emphasizes the importance of chemical identity confidentiality. See, e.g., MCA comments in the proposal (p. 319), and CMA comments on the reproposal (p. 138). It is especially important in the pre-commercial stages. See, e.g., ADL's Industry Interviews.

The inventory options do not affect the timing options considered above; they will still occur.[30] The rationale for the option to add the chemical to the inventory by generic name is that most of the submitter's competitors, as a matter of course, will maintain an up-to-date inventory. If the specific chemical identity was placed on the inventory, it would be readily available to the submitter's competitors. On the other hand, adding only the generic name to the inventory would require competitors to consult the public record to discover the specific chemical name (i.e., public disclosure, which is separate from addition to the inventory, is made by placing the specific chemical identity in the public file, not by publishing it as an individual document). The generic option, in effect, does not prevent competitors from obtaining the specific chemical identity; it merely makes the competitor's ability to gain the information slightly more difficult. At best, this protection gives the submitter a little extra time to keep the specific chemical identity obscured from competitors.

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[30] Note, however, that there will be an inconsistency if the chemical identity is added to the inventory when commercial manufacture begins and public disclosure is not made until commercial distribution. In such a situation, delaying public disclosure until distribution has little effect.

CHAPTER 2

CUSTOMER CONTACT

The thorough evaluation of the environmental risks of producing any new chemical may require EPA to obtain information from those who purchase the chemical. Information sought could include data on exposure of workers during processing, environmental release, disposal, and use by the general population. To obtain this information, EPA has proposed several alternative rules. In this paper, we assess the relative costs to industry of these alternatives on the basis of information in the public record.

In the following sections, we will:

- specify the options under consideration,
- specify the types of costs incurred by industry, both submitters and customers, and
- estimate the relative burden to industry of each option for each type of cost.

It is difficult to discuss customer contact in isolation from the other issues. Both supplemental reporting and confidentiality play a role in the discussion of customer contact. In our discussion, we assume that the Agency may obtain supplemental information and that confidentiality provisions will protect confidential data from disclosure. The interactions among the issues are discussed in the section on comprehensive program options.

CUSTOMER CONTACT OPTIONS

The options proposed by EPA are:

- Option 1: January 10 Proposal. The submitter must contact all customers in writing, unless he believes that the information is already contained in the notice. If he believes that contacting all customers would be duplicative, he can contact a representative sample. The submitter must request each person contacted to complete a Processing and Consumer User form. The persons who must be contacted are:
  - -- firm customers--persons party to a contract to obtain the substance from the submitter;
  - -- likely customers--persons who have contacted the submitter and indicated an interest in obtaining the substance;

-- Potential customers--persons who have obtained a sample of the substance and who have indicated an interest in purchasing it; and

-- Possible customers--persons whom the submitter has contacted or intends to contact and whom the submitter firmly believes will purchase the substance during the first three years of commercial production.

The submitter must provide EPA with a list of the names of the customers as well as with any customer contact forms returned to him (the customers are not required to respond and they may respond either to EPA or to the submitter).

- Option 2: October 16 Proposal. Under option 2, the submitter would have to indicate in the notice the number of customers who have made a firm commitment to purchase the substance for a category of use unknown to him and the percentage of estimated production that such customers are expected to purchase during the first three years of production. EPA may subsequently ask the submitter to voluntarily provide the agency with the names and addresses of customers; EPA can then contact customers directly. A variation on this option is to require the submitter to indicate on the notice the number of all expected customers whose use of the product is unknown to him, not just those who have made a firm commitment to purchase the substance, and the percentage of estimated production that such customers are expected to purchase during the first three years of production.

- Option 3: The submitter would have to indicate in the notice the estimated number of customers for all categories of use, including unknown categories, as well as an estimate of production volume expected for each of those uses for the first three years. EPA may ask the submitter to voluntarily provide the agency with the names and addresses of customers. Or EPA may require that a customer list be furnished, under the supplemental reporting provisions. EPA can then contact customers directly.

- Option 4: In addition to the information provided under option 2, the submitter is required to provide EPA with a list of the names of potential customers. The customers can be divided into four categories, as in option 1.

- Option 5: Elimination of all customer contact provisions. The submitter need not contact customers, provide a customer list, or estimate the number of customers in various categories of use.

Evaluation Framework

In this section, we evaluate the direct costs to industry of each option. Option 5, elimination of all customer contact provisions is used as the baseline from which to assess the other options. Under options 1 and 4, the effect of using different definitions of "customer" will be assessed. These definitions of customer will be:

(A) firm customers only;
(B) firm and likely customers;
(C) firm, likely, and potential customers;
(D) firm, likely, potential, and possible customers.

The direct costs to the industry are seen as the following:

- cost of compiling customer lists;
- direct cost of contacting customers;
- delay in the introduction of new chemicals;
- uncertainty;
- cost to customers of providing information; and
- reduction of demand for new chemicals.

Because each cost will vary depending on the behavior of submitters and EPA, the nature of other section 5 rules, and the nature of specific chemical markets, it is not reasonable to specify the exact costs attributable to the customer contact provisions. It is reasonable, however, to specify relative costs of each option to industry under each type of cost, comparing each option against the baseline (option 5). The result is a matrix of options and costs, shown in Exhibit 2-1. The justification for the entries in the matrix is given in the rest of this section.

COST OF COMPILING CUSTOMER LISTS

The cost to a chemical producer of compiling a customer list depends on EPA's definition of "customer". The four categories of customers are listed under option 1, and one or more of those categories comprises the customers referred to under the other options. Therefore, in determining the cost of compiling the customer list, we examine the special characteristics of each of these categories of customers.

The cost of compiling a customer list is largely determined by the internal recordkeeping practices of chemical firms and how many customers are to be contacted. For example, if chemical firms normally compiled lists of customers for each product and the firm's definition of customers were the same as EPA's definition, the additional cost of compiling and submitting a customer list to EPA would involve only minor administrative and postage expenses. Or, if information on each customer for each chemical were kept on a separate card or sheet, compiling a customer list would be only slightly more expensive than the previous case. The firm would need only assemble the separate documents and type a list. If the documents were not kept in some

EXHIBIT 2-1

RELATIVE COSTS OF CUSTOMER CONTACT OPTIONS 1-4, AS COMPARED TO OPTION 5

Option	1				2	3	4			
Customer[a] Definition	A	B	C	D			A	B	C	D
Cost to Industry										
Compiling Customer List	2	3	3	4	2	2	2	3	3	4
Direct Cost	2	2-3	2-3	3	1	1	1	1	1	1
Delays	2	2	2	2	2	2	2	2	2	2
Uncertainty[b]	3	3	3	3	3	3	3	3	3	3
Cost to Customers	3	3	3	3	2	2	2	2	2	2
Reduction in Demand	3	3	3	4	2	2	2	2	2	3

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1 = Negligible
2 = Low
3 = Medium
4 = High

[a] The four definitions of customer are:

- (A) firm customers only;
- (B) firm and likely customers;
- (C) firm, likely, and potential customers;
- (D) firm, likely, potential, and possible customers.

[b] = Initial costs--should decrease over time.

central location, but instead were scattered among a number of salespeople, the cost would increase, especially if the documents were located in different plants. (The firm would have to assemble the documents in some central location.) Furthermore, if there were no written records specifying exactly who is a customer for each chemical, it would be necessary for that person responsible for completing the notice to contact each salesperson and elicit the information in writing.

Information about firm customers--those who have signed contracts--will be listed on some written document. A customer list may not exist and, depending on the time when the notice is filed, the documents containing the names of customers may not be gathered in a central location. But a written record should exist. A written record should also exist for likely customers--those who have obtained samples--though the record may not indicate if the person is interested in purchasing the chemical, and the records may not be kept in one central location. Information about potential customers--those who have contacted the submitter and indicated an interest in obtaining the substance--and about possible customers--those whom the submitter has contacted or intends to contact and whom the submitter firmly believes will purchase the substance during the first three years of commercial production--may not be kept in written form.

The total cost of compiling a customer list cannot be found merely by adding the costs associated with the current method of internal recordkeeping. A firm might find it less costly to change its method of recordkeeping to produce the type of records required by section 5. It is unlikely that we will be able to estimate the cost of compiling a customer list if internal recordkeeping is altered, because we would need to know more about chemical companies' data management systems before we could make such an estimate. Therefore, we will assume that internal recordkeeping is not altered. We would note, however, that the cost of compiling a customer list, based on current recordkeeping practices, is an upper bound of the actual costs, because firms might conceivably alter their recordkeeping procedures and lower their costs.

We should also note that the firm has some control over the cost of providing a list, because the decision that someone is a likely, potential, or possible customer is, to a certain extent, a subjective judgment, especially when possible customers are involved. An examination of the language defining possible customers--"whom the submitter firmly believes will purchase the substance during the first three years of commercial production"--shows the amount of discretion available to the submitter in determining who are possible customers.

Under options 2 and 3, EPA may ask the submitter to voluntarily provide the names of customers in those cases in which the chemical is under detailed review; EPA estimates a small number of such cases.[31] Under options 1 and 4, complete lists of customers are to be provided in all cases. Because the lists are required in four or five times as many cases under options 1 and 4 than under options 2 and 3, the costs associated with the latter options should be substantially smaller.

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[31] 44 Federal Register 59765 (October 16, 1979). EPA anticipates that it will be able to decide that most chemicals require no further regulation on the basis of the information provided in the notice and a literature search conducted by EPA staff.

The costs of options 1 and 4 depend greatly on just who is included in the list of customers and on the way in which records are kept in the chemical industry. We estimate that if only firm customers are included, the relative cost is likely to be small, because written records must be kept on customers with signed contracts. If likely customers are added, the cost could increase substantially, since it is less probable that a written record of these customers would exist. The addition of potential customers should not increase the cost much since some written record of these customers should exist. However, the addition of potential customers could make the relative cost quite large, because the firm might well have to piece together information from a large number of its employees in order to compile such a list.

Direct Cost of Contacting Customers

Only under option 1 does the submitter bear the cost of contacting customers. Under the other options, the cost of contacting customers is borne by EPA. With any recordkeeping system, under option 1 the costs, consisting of postage and the administrative burden, will be virtually proportional to the number of customers contacted. If the number of customers is large and the producer believes that the information they provide will be duplicative, the producer can contact a sample. This should reduce somewhat the cost of customer contact.

Under options 2, 3, and 4 the contact cost is no different from the baseline, because EPA bears the cost. Under option 1, the costs to the submitter vary with the number of customers contacted. We therefore expect direct costs of contacting customers to be low if only firm customers are included, low to medium if likely and potential customers are included, and medium if all customers are included.

Arthur D. Little, Inc. estimated the cost of completing the notice form. However, we can not extract from those estimates the cost of the information that must be submitted under the options 2, 3, and 4. In the ADL estimates, the cost of questions on customer use is grouped wth other questions and the costs cannot be disaggregated.

Delays in the Introduction of New Chemicals

There are two ways in which the customer contact provisions could cause a delay:

- The process of obtaining information from customers results in an extension of the 90-day notice period. As noted above, customer information is usually important only when the substance is under detailed review; in these cases, the notice period will most likely be extended anyway. It is possible that in some cases which are not under detailed review, customer information might be important and delays could occur while the information is acquired. But analysis of the relevant options (options 2, 3, and 4) suggests that delays should occur very infrequently. Therefore, in these cases, the customer contact provisions will most likely not cause any delays in the introduction of a chemical.

- When little is known about the chemical, customers may be contacted to determine if detailed review is necessary. In these cases, if customers respond slowly, the review period might be extended and the introduction of the new chemical delayed. Similarly, customers might conceivably supply information that would subject the chemical to detailed review.

As stated above, options 2, 3, and 4 would result in only a small chance of delays in new chemical introduction; the overwhelming number of customer contacts would involve chemicals subjected to detailed review, for which the notification period would already have been extended. Under option 1, the customers would be contacted routinely so the process itself would not result in delays. If customers did not provide information under option 1 voluntarily, EPA might seek the information under the supplemental reporting provisions, and the use of these provisions might cause an extension of the notice period and a delay in the introduction of a new chemical. But again, supplemental information will only be requested in those cases in which the substance comes under detailed review. The total cost, therefore, is likely to be small.

Uncertainty

In addition to the costs which may actually be imposed upon chemical producers and consumers, uncertainty about how EPA will implement whatever option is eventually chosen and uncertainty about what those costs will be, will impose costs on chemical producers. Because of this uncertainty, firms may devote more or fewer resources to the section 5 notice process than are required, and they make take actions that result in unnecessary delays. Some of this uncertainty is inevitable and will diminish as the Agency and industry gain experience with the Act and with each other's actions related to the Act. But some residual uncertainty and associated negative consequences will remain.

With the exception of option 5, which contains no provisions for customer contact, each of the options allows EPA to retain a great deal of discretion in the degree to which it will contact customers and, therefore, in the costs it imposes on the industry. We estimate that the initial costs of uncertainty should be medium under all options, but should decrease over time. However, it should be noted that the estimate of the level of uncertainty costs is itself quite uncertain.

Cost to Customers

When customers choose to provide information to EPA rather than forego use of the chemical, they will incur costs in providing information to EPA. The costs include more than just the time and resources necessary to provide EPA with the answers to its questions; the costs also include the risk that important information will become available to competitors. We have assumed that the same confidentiality provisions that apply to information obtained from producers will also apply to information obtained from customers. The confidentiality provisions are analyzed in another section.

As noted above, under options 2, 3, and 4, EPA anticipates that customers will be contacted only if the chemical is under detailed review, which should occur relatively infrequently. In those cases, the costs should be small. Under option 1, customers are contacted and EPA can require customers who did not respond voluntarily to provide information to EPA. Because customers will be providing information to EPA in many cases under option 1 (the number depends on the extent of voluntary responses by customers) in which they would not provide information under the other options, the cost of option 1 will be greater.

Reduction of Demand for New Chemicals

The costs incurred by customers may result in a downward shift of the demand curve for new chemicals. Under the customer contact provisions, the customer has the option of refusing to provide the information voluntarily. However, the possibility exists that if the information is not provided voluntarily, EPA will make worst case assumptions,[32] leading to restrictions on the production of the chemical. Thus, the firm must report to EPA if it is identified as a customer. The need to provide this information will act as a deterrent to firms with an interest in the new chemical; they will be dissuaded from buying it. The result will be a loss of profits and sales for the producer of the new chemical.

It is important to note that a potential customer cannot be compelled by EPA to provide information during the notice period. Although the customer is not required to provide information, he is faced with a choice: either provide the information requested or risk unfavorable activity. Both actions impose costs on the customer; either he must incur the costs of providing information to EPA or forego the chance to use a new, presumably more efficient chemical. The customer's choice should depend on his valuation of the chemical. If he believes the value of the chemical outweighs the cost of providing information to EPA, he will pay for providing information; if not, he may forego use of the new chemical. Therefore, there will be a downward shift in the demand curve. Consequently, a decrease in the introduction of new chemicals in those cases in which customers are contacted will occur. But those chemicals that the customer foregoes are, in all likelihood, chemicals whose expected benefits to the customers are small.[33]

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[32] 44 Federal Register 2244 (January 10, 1979).

Even if some new chemicals are not introduced because customers are discouraged from purchasing the chemicals by the burden of providing information to EPA, it is not clear to what extent the chemical industry as a whole suffers any loss. Certainly the firm which loses customers suffers a loss in sales and income, but the producer of the old chemical which would have been replaced by the foregone innovation does not lose sales and income. In this case, section 5 serves only to redistribute sales and income among chemical producers. The chemical industry as a whole experiences a loss only when the foregone chemical would have replaced something other than a chemical (perhaps even expanding demand because of cost reduction) or when imports take over a market because a new chemical is not produced in the United States. It is important to note that no producer of a new chemical will be more or less disadvantaged than other producer of a new chemical, because the same requirements apply to all new chemicals.

There is another possible consequence of the customer contact provisions which could reduce the demand for new chemicals from the original innovating companies. A customer who is also a potential competitor may be alerted to the development of a new chemical; he might preempt the innovator by producing the chemical itself instead of purchasing it from the innovator. Such a circumstance is only a danger for possible customers--those whom the producer firmly believes will purchase the substance during the next three years--because customers in the other three categories must, by definition, already know about the chemical. In addition, by the time customers are contacted, non-confidential information on the submission is about to be placed in the Federal Register and a sanitized version of the notice made available to the public.[34] Therefore, the danger of preemption is increased only to the extent that the definition of customers includes possible customers and to the extent that possible customers, who are really interested in preempting the innovator, would not be alerted to the new chemical as a result of the Federal Register notice. The extent of the danger cannot fully be determined without extensive information about chemical industry innovation and marketing, but we expect it to be small, because the number of cases in which the necessary conditions for preemption exist will be quite small. It is possible that competitors will obtain useful information from the notices, but the potential disclosure of confidential business information is a cost of the confidentiality policy and is not discussed here. However, the additional potential for disclosing confidential business information due to the customer contact provisions should be small, because in only a few cases would additional information actually be made available to competitors through the customer contact process.

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[33] The issue of the importance of innovation to both society and the chemical industry and the effects of section 5 on innovation is a central part of the overall analysis of the economic effects of section 5. A methodological framework for this analysis has been developed and was published in the Federal Register, and the discussion of innovation found here is consistent with that methodology. We recognize that additional analysis is needed in this area.

[34] A submitter must certify on the notice form that he has contacted his customers. That contact must have occurred before the notice is submitted, but it appears that contact on the same day that the notice is submitted would not violate the rules. The Agency must publish a Federal Register notice five days after receipt of the form from the submitter.

Because the costs imposed on customers will be greater under option 1 than under the other options, the costs of reduction in demand will be greater under option 1 than under the other options. In addition, because of the possibility that potential competitors may preempt the initial developer, the cost of customer definition option D, under options 1 and 4, in which all four categories of customers are included in the customer list, will be greater than the costs of the other customer definition options.

SUMMARY

Under option 1, EPA requires information from customers in many cases in which information would not be required under the other options. Consequently, under option 1 the costs imposed on the industry are substantially larger than under the other options. The extent of the difference depends on the definition of customer that is adopted. Option 4 presents some of the same problems as option 1, but in a less extreme form; customer contact is not required in all cases, but provision of a customer list is. Under option 5, all costs to the industry are avoided. The differences between options 2 and 3 are very small. In fact, the only difference is that under option 3, the submitter would have to indicate on the form the estimated number of customers for all categories of use, including unknown categories; under option 2, the number of customers for unknown uses only would be estimated. The difference in cost between options 2 and 3 is trivial because making the additional estimate required under option 3 requires little additional time. There is little difference in the cost to industry of reporting all uses as opposed to unknown uses.

CHAPTER 3

DEFINITION OF IMPORTERS

Under section 720.10(a)(2) and (b)(1) of the January 10, 1979 proposed rules, "any person who intends to import" a new chemical substance is required to submit notification to EPA. Import transactions vary in the number and type of parties involved and in the methods of importation. Some parties involved in the import process may be unaware of information about the chemical substance. There is a variety of participants in importation, and some of the information required on the notification form is highly technical. Therefore, EPA is considering which parties should be responsible for submitting notification on new chemical substances that are imported.

IMPORTER DEFINITION OPTIONS

The contractor has evaluated five alternatives for designating persons responsible for submission of section 5 notification on imported new chemical substances:

Option 1: Define Importer as the Consignee. This definition would identify one person as responsible for notification, although the consignee would not necessarily possess enough information to submit an adequate notice. The consignee is the person to whom goods are delivered, and may be anyone involved in importing a chemical, including a retailer or broker.

Option 2: Define Importer as Consignee and Impose Upon Him an Obligation to Obtain the Information Required by the Rules and Forms from Other Persons. These other persons, including identifiable future users and processors of the chemical, would be expected to provide information to the submitter or EPA, if information is known or fairly easily ascertainable. Such a system would provide EPA with more information than might be submitted by the consignee alone.

Option 3: January 10th Definition of Importer--Section 720.2. "Importer" means any person who imports a chemical substance or a chemical substance that is part of a mixture or article into the Customs Territory of the United States. The definition of "importer" includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his behalf. "Importer" also includes as appropriate:

- the consignee;
- the importer of record;
- the actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20; or
- the transferee . . .".

This definition is derived from the definition of importers used by the U.S. Customs Service which defines importer as "the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his behalf." (19 CFR 101.1 (k)). According to this definition, each of the persons listed would be responsible for ensuring that notification is submitted to EPA; a single person with responsibility for submission is not identified.

Option 4: Define Importer as "The Person Who Imports, or Knowingly Causes to be Imported a Chemical Substance". The person ordering a chemical substance in a domestic transaction would knowingly cause the substance to be imported if he places an order knowing it will result in the importation of the substance. This definition is similar to one adopted by the Customs Service for reporting requirements and was suggested by the American Importers Association in their comments on the January 10th proposal.

Although this definition would theoretically require the most knowledgeable person to submit notification, in reality it might prove difficult for both the Agency and the parties involved to identify the single submitter responsible for notification. This definition also might not reach the most knowledgeable person.

Option 5: Clarify January 10th Definition of Importer in the Rule Itself and in Other Relevant Documents to Indicate that EPA Will Only Allow the "Principal Importer" Involved in Import to Submit the Section 5 Notice. The "principal importer" is the person who, knowing the new chemical substance will be imported, selects the identity and the total amount of the chemical substance to be imported. The "principal importer" is also likely to be the person who will process, use, or distribute the chemical.

This clarification would aim at getting the most knowledgeable person to submit notification and is intended to reach a single individual. EPA would further identify the responsible submitter by providing examples and instructions for different types of import transactions.

Evaluation Framework

The five options are evaluated on the basis of costs to industry. These costs are seen as the following:

- Costs of Notice Submission, including out-of-pocket costs of filling out the notice form, and bargaining, delay, and costs associated with uncertainty when no single submitter is easily identifiable.
- Post-Submission Costs: dollar and delay costs of clarifying supplemental information, potential for trade secret disclosure, and action under section 5(e).

Exhibit 3-1 shows a matrix of the options and their relative costs and is discussed more fully below. It is assumed that the notification form submitted for all five options is the October 16th reproposed form.

EXHIBIT 3-1

COSTS TO INDUSTRY

	Option 1	Option 2	Option 3	Option 4	Option 5
Coverage	narrow	broad	broadest	broad	narrow
Cost of Notice Submission:					
Out of Pocket	1	2	2	1	1
Delay, bargaining	1	2	2	1	1
Uncertainty (liability)	0	2	3	2	1
Post-Submission Cost					
Supplementary Reporting	3	2	2	2	1
Section 5(e) Action	3	2	2	2	1
Trade Secret Disclosure	1	3	2	1	1

Note: 0 = no cost, 1 = lowest cost, 2 = next lowest cost, etc.

COVERAGE

As outlined in Exhibit 3-1, coverage refers to the number of people that would likely be involved in the preparation and submission of the notice form. Option 3 requires each of the parties included in the definition of importer to be responsible for submission and, therefore, has the broadest coverage. Options 2 and 4 can include more than one individual submitter, if (under option 2) the importer must contact more knowledgeable persons in order to complete the form, or if (option 4) uncertainty exists as to who knowingly caused a chemical to be imported. Both options 1 and 5 are more specific in pinpointing a single submitter and, therefore, have the lowest coverage.

Many of the options evaluated here do not specify exactly how many people would be involved in the notification process or whom these parties would be. It is difficult therefore, to estimate coverage as well as costs. Under any of the options, the behavior of the parties involved cannot be predicted with certainty. For example, under option 1 the submitter is the consignee of the imported chemical. However, if the consignee is a broker and does not receive assistance from the customer in filling out the form, the broker will refuse to handle new imported chemicals. The consignee/submitter would then become someone more knowledgeable about the chemical, and option 1 might resemble option 4 or 5.

In terms of the actual entities or people involved in import transactions, it is useful to characterize participants as follows:

- brokers who clear merchandise through Customs. Some brokers act also as freight forwarders, arranging for transportation and insurance of the merchandise;
- trading companies (including manufacturers' representatives) generally of small size and varying familiarity with the products they handle; and
- domestic chemical companies who may import new chemicals for use in manufacturing and processing, or to distribute them to customers.

The primary distinction among these entities in terms of reporting requirements is between importers that act as expediters or agents of the import process, and importers that intend to process, use, or distribute the imported chemical themselves. The latter presumably would have the technical knowledge to submit a section 5 notice. The former type of importer could not submit an adequate notification; rarely, in fact, would this type of importer even be aware or able to determine that chemical shipments in a consignment are "new."

Methods of import vary. Most of the largest chemical companies have separate importing departments and act as their own importers. Other large companies employ brokers to handle the imported goods. If they are regular importers, they likely will have established relationships with a custom house broker. Data were not available on what proportion of companies clear their own merchandise compared to those that use brokers. Cost factors, the degree of oversight of merchandise entering the country, and the distance from the port of entry to the company plant, may all be factors in the decision to use a broker.

Factual information is not available for small and medium-sized domestic chemical companies. They may not have importing experience and often may rely on larger chemical companies to import the chemicals they need. Occasional importers are likely to use brokers.

Trading companies fall somewhere between brokers and chemical companies in terms of the amount of knowledge they would have about a new chemical import. Trading companies are usually small companies that specialize in buying and selling goods. At times they match up known buyers and sellers, at times they find either a product or a market. Trading companies do not use the chemicals they import, nor would they usually develop a wide distribution system for selling a chemical. The extent of their knowledge about a chemical would vary. It is possible, for example, that in some cases they would know the chemical identity of an imported substance, while in other cases they might not.

As far as new chemicals are concerned, it is unlikely that a trading company would be involved unless it had firm customer commitments. Trading companies are usually high-turnover, low inventory operations, and would not be able to afford to import and warehouse new chemicals while searching for markets among domestic companies.

If a trading company does have customers for the new chemical, responsibility for submitting notification to EPA would depend on the definition of importer and the circumstances of the transaction.

COSTS TO INDUSTRY

Costs of Notice Submission

The notice form to be submitted under each of the five options is assumed to be the October 16th reproposed form. The costs of completing the form are estimated at $900 to $8900 by ICF on the basis of ADL's costs estimates for other firms. (The domestic manufacturers' form is estimated to cost $1200 to $8900; in some cases the importer will omit the section on exposure at industrial sites, estimated to cost $300 to $2100 to complete. Therefore, the lowest estimate will be $900 and the highest will be the same as for domestic manufacturers, $8,900).

The out-of-pocket cost of submitting the form is assumed to be equivalent under each option, although increased costs of gathering the information may shift the cost towards the high end of the estimated range for options 2 and 3. Similarly, under options 2 and 3, delays may occur in preparing the form because of the need to contact other parties. Bargaining costs may also be incurred as importers negotiate assistance from more knowledgeable parties. Uncertainty costs may be present under option 5, but are likely to be larger under options 2 and 4, where the most knowledgeable persons or the person who knowingly caused importation may be hard to identify. Uncertainty costs are highest for option 3, where parties may not know all the persons who are responsible for submission, and where some parties may be unwittingly exposed to liability for failure to submit notification.

Finally, there is the possibility of a continuing cost to importers of loss of business if domestic companies reduce their level of import demand. However, this potential cost would not likely be significantly affected by the choice of importer definition from among the five options.

Post-Submission Costs

Potential costs which may be incurred following notice submission include the possibility of out-of-pocket costs and delays due to supplementary reporting requirements, section 5(c) and 5(e) actions, and trade secret disclosures. The first two sources of additional costs are affected by the choice of importer definition to the extent that additional data either existing, 5(c), or to be created, 5(e), is needed. It is possible that notices submitted under option 1 will be inadequate, although option 5 notices will contain better information. However, it is difficult to predict the relative consequences of choosing among the various options.

Trade secret disclosures may be more likely to occur when several parties are submitting information, particularly when the submission is not well coordinated. The various parties who may provide information directly to EPA and the party who actually submits the notice may not be sufficiently aware of all the confidentiality concerns of all parties involved. This situation is most likely to arise under options 2 and 3 where there may be some uncertainty about which parties are involved and where a high degree of participation may be necessary to produce an adequate notice.

SUMMARY

Significant differences among the five options discussed occur mainly in the extent of responsibility for notice submission and the costs of notice submission. These costs would weigh most heavily on less knowledgeable individuals who would have to obtain the information required on the form from others or negotiate for assistance from other parties. Although some adjustments may occur in methods of importation because of section 5 notification requirements, they are not likely to be significantly affected by the choice of importer definition.

CHAPTER 4

IMPORTER CONTACT OF FOREIGN MANUFACTURERS/SUPPLIERS

Because of the nature of the import business and the limited information that is available to some importers on new chemical substances, an adequate section 5 notice in many cases will require information that can only be supplied by the foreign manufacturer of a new chemical substance. In some cases it is expected that the foreign manufacturer/supplier will assist in the preparation of the notice form, however this is not likely to be true in general. The various types of importers will usually have different types of relationships with their foreign manufacturers/suppliers--their "upstream" contacts.

UPSTREAM CONTACT OPTIONS

Two issues are being considered by EPA with regard to obtaining information from foreign manufacturers and suppliers about new chemical substances being imported into the United States. They are:

- whether mandatory contact with foreign manufacturers and suppliers should be imposed on importers, and
- the extent of information that should be requested of upstream contacts.

The following four alternatives are being evaluated:

Option 1: mandatory contact and the Foreign Manufacturers/Suppliers Form outlined in the January 10 proposal;

Option 2: mandatory contact and a Foreign Manufacturers/Supplier Form revised to be consistent with the forms in the October 16 reproposal;[35]

Option 3: mandatory contact and the request of only health and environmental effects data and risk assessments from foreign manufacturers/suppliers;

Option 4: no mandatory contact by importer.

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[35] The form outlined in the January 10 proposal includes the following information which would be omitted in the revised form: names and addresses of related companies; some production and marketing data; chemical use assumptions; information about foreign restrictions or bans on the production of the chemical; and a detailed outline of submitted risk assessment data. None of these questions are included on the October 16 reproposal of the domestic manufacturers' form.

Evaluation Framework

An evaluation of costs to industry of each option is presented in this section using option 4, which does not impose mandatory contact, as a baseline.

The direct costs to industry include costs to parties involved as importers as well as costs to foreign manufacturers. It should be noted that although importers would be required to contact the foreign manufacturer and supplier of the new imported chemical substance, the cooperation of the foreign manufacturer or supplier is entirely voluntary.

The direct costs to the industry are seen as the following:

- costs to importers of contacting and requesting information from foreign manufacturers/suppliers; and
- costs to foreign manufacturers/suppliers, including out-of-pocket costs of submitting information, and the possibility of trade secret disclosure.

Exhibit 4-1 presents a chart of the relative costs to industry of each option.

EXHIBIT 4-1

COSTS TO INDUSTRY

	Option 1	Option 2	Option 3	Option 4
Costs to Importers	1	1	1	0
Costs to Foreign Manufacturers/Suppliers:				
Submission of Information[a]	\$3,000-11,600	\$1,800-7,200	\$300-1,500	\$0
Trade Secret Disclosure	3	2	1	1

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[a] See Exhibit 4-3 below.

Note: For ordinal estimates, 0 = no cost, 1 = lowest cost, 2 = next lowest cost, etc.

COVERAGE

The analysis of this issue is based on the assumption that foreign manufacturers/suppliers will be from Japan or the European Community where there are new chemical notification programs and where, consequently, much of the information requested would be incremental to existing, available information. Before proceeding to the analysis, it is worthwhile discussing this assumption in greater detail.

Sources of Imports

Exhibit 4-2 shows the percentage of total value of chemical imports by foreign origin for all chemicals and organic chemicals for 1975-1978. As can be seen in the final column of the table, Japan and the European Economic Community countries account for approximately half the annual imports of all chemicals, and about 73 percent of annual imports of organic chemicals. In terms of all chemicals, Canada remains the U.S.'s largest single-country trading partner. The percentage of imports of organic chemicals from Canada is roughly the same as from West Germany or Britain, and about five percent less than Japan. There would be a serious error in the assumption used here, if Canada, or the other countries outside Japan and the EEC which account for 15-25 percent of imports, were major sources of new chemicals. However, although it is difficult to document, it is widely agreed among participants in this segment of the industry that most new chemical imports at present originate in Western Europe and Japan.

EXHIBIT 4-2

PERCENT OF TOTAL VALUE OF IMPORTS (F.A.S. VALUE), 1975-1978

Chemicals	Canada	West Germany	EEC	UK	Japan	Other	EEC and Japan
1975 all chemicals	23.5	N/A	40.2	8.4	10.5	25.8	50.7
organic	7.4	N/A	57.2	9.0	22.5	12.9	79.7
1976 all chemicals	27.0	N/A	40.6	9.9	8.3	24.1	48.9
organic	10.9	N/A	55.7	9.8	17.7	15.7	73.4
1977 all chemicals	26.7	11.0	40.3	10.2	8.6	24.4	48.9
organic	13.8	14.2	56.2	9.6	16.6	13.4	72.8
1978 all chemicals	28.1	12.4	43.4	11.4	8.7	19.8	52.1
organic	12.5	13.9	54.8	11.8	16.3	16.4	71.1

Source: U.S. Department of Commerce, Bureau of the Census, Highlights of Exports and Imports, Report FT 990 (Washington, D.C.: Government Printing Office, December 1975, 1976, 1977, 1978).

Foreign New Chemical Notification Programs

The assumption used here is that the Foreign Manufacturers/Suppliers Form would be requesting information generally available and previously submitted in foreign notification programs. Although most foreign notification programs (with the exception of Japan) are pre-market rather than pre-manufacture programs, and although notification under the European Directive is not due to take effect until March, 1982, in most cases the information requirements are or will be similar.[36] Testing requirements in foreign countries may increase the amount of useful information about new chemicals that could be available from foreign manufacturers. However, small volume chemicals (under one ton annual production) do not require notification under EEC guidelines.

Costs to Industry

An assessment of the costs to industry imposed by any of the four options is made difficult by the fact that cooperation on the part of foreign manufacturers/suppliers is voluntary. Even an assessment of the relative costs of each option must depend on some assumptions about the behavior of industry parties. For example, as shown in Exhibit 1, the cost to a foreign manufacturer of completing the January 10th Foreign Manufacturer/Supplier Form (option 1) is much greater than submission of only health and safety data (option 3). However, a foreign manufacturer, under option 1, is free to submit only health and safety data and not incur the larger cost. It is difficult to predict, however, whether the foreign manufacturer would submit more information if asked for it, or whether the more onerous request would discourage submission of some or possibly any information.

Costs to Importers

Under the January 10th rule provisions regarding mandatory contact by importers, the direct cost to importers involves only the written request of information from the foreign manufacturer/supplier. In cases where the importer does not know who the manufacturer is, he must request the supplier to provide the identity of the manufacturer. Foreign manufacturers and suppliers are not required to cooperate. But the information they supply would reduce the likelihood of EPA imposing supplementary reporting requirements. The direct costs to the importer of contacting the foreign manufacturer/supplier and certifying to that contact are negligible. These rule provisions are applicable to options 1, 2, and 3.

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[36] EEC Council Directive of 18 September 1979, printed in Official Journal of the European Communities, L259, Vol. 22, 15 October 1979. See also: Mitre Corp., Information Required for Regulation of Toxic Substances, Vol. 1, June 1978 (NTIS PB-288 023).

Indirect costs to importers could involve foregoing possible business because of the expectation that the foreign manufacturer will not cooperate and adverse action will be taken against the chemical. They could also involve the loss of import business as a result of concern by the foreign manufacturer of trade secret disclosure. This concern is discussed below in greater detail. However, there appear to be no significant differences among the four options in the extent to which these indirect costs are affected. These indirect costs, which represent the possibility of loss of business, are present whether or not mandatory contact is imposed and whatever amount of information is requested of the foreign manufacturer.

Costs to Foreign Manufacturers/Suppliers

Direct out-of-pocket costs are incurred by foreign manufacturers/suppliers if they elect to submit the requested information. These costs vary across the four options and are outlined below in Exhibit 4-3. The costs shown represent the estimated costs of completing the entire notification request. However, these costs are based on estimates for similar forms submitted by domestic manufacturers. Foreign manufacturers may already have much of the information requested available because of prior submission to a foreign new chemical notification program. If they do, the direct costs shown here may be overestimated.

With regard to option 4, no mandatory contact by the importer, it is not possible to attribute any one cost figure to the foreign manufacturer/supplier. Certainly, in some cases, the foreign manufacturer/supplier will be asked by the importer to provide information, and in other cases, the foreign manufacturer may even assist in the preparation of the importer's form. Under this option, as well as the other three, submission of insufficient information increases the risk of added costs and delays. Importers and foreign manufacturers will calculate these risks and incur costs of submitting information depending on the expected return from the new chemical substance. For some products, for example, the U.S. market may represent the most significant area of marketing opportunities, and the costs of providing all requested information to EPA would be readily borne by the foreign manufacturer.

It would not be feasible to attempt to estimate what portion of new chemical imports might be affected by these direct costs. Indeed, the dollar cost of submitting information may not be the significant burden on foreign companies exporting to the U.S. Rather, the confidentiality issue could be the more powerful inhibitory factor. There are two aspects to this issue: the first is the general confidentiality issue of how confidential business information will be treated under TSCA. This issue is discussed in a separate document. Essentially, the burden will be on submitters to assert and substantiate confidential business information. Even for some confidential business information asserted and substantiated as confidential, a "masked" disclosure of the confidential business information will be required. In addition, Japan and Canada treat all submitted data as confidential, so that fear of trade secret disclosure might inhibit imports of new chemicals from those countries.

EXHIBIT 4-3

COSTS OF SUBMISSION OF INFORMATION

Option 1. Foreign Manufacturer/Supplier Form, January 10, 1979.

Section of Foreign Manufacturer/Supplier Form	Information Category	Comparable Section of Proposed Domestic Manufacturer Form (Source of Required Hours)	Hours Clerical ($10/hour)	Hours Technical ($25/hour)	Hours Managerial ($50/hour)	Cost (in dollars)
I.A, I.B	General Information and Chemical Identity	I.A minus items 5c, 6, and I.B	3 - 5	4 - 8	1 - 1	180 - 300
I.C	Production and Marketing Data	I.C	2 - 6[a]	4 - 24[a]	2 - 6[a]	220 - 960
I.D	Federal Register Notice	I.D	2 - 4	4 - 16	2 - 4	220 - 640
II.A	Risk Assessment Data	II.A	10 - 80	16 - 120	8 - 20	900 - 4,800
II.B	Risk Analysis	III.A	10 - 20	10 - 80	10 - 20	850 - 3,200
II.C	Structure/Activity Relationships	III.B	10 - 20	10 - 40	5 - 10	600 - 1,700
					Total Cost	$2,970 - 11,600

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[a] Production and marketing data are requested in section I-C of the foreign form. ADL's hour estimates for section I-C of the domestic form were considered in estimating the hours for section I-C of the foreign form. However, from observation of the two comparable sections, it is clear that they are substantially different. Although information requested in the domestic form's section is also requested in the foreign form's section, the foreign form requires additional information not required in the domestic form. The domestic form only involves the reporting of new chemicals (or chemical processes) but the foreign manufacturer/supplier form addresses either of two cases: (1) the reporting of new chemicals or (2) the reporting of chemicals intended for import into the United States which have previously been manufactured abroad but have never been introduced in the United States. In case 1, the information requirements are the same as those for the domestic form, and so ADL's hour estimates are applicable. In case 2, however, the information of case 1 is required plus additional information on past marketing and use abroad.

The minimum hours that ADL attributed to production and marketing data for the domestic form were two for clerical, four for technical, and two for managerial labor. Because the requirements of this section of the domestic form are the same as those under case 1 for the foreign form, and since case 1 requires less information than case 2, these hours were used to represent the minimum hours for the foreign form's section on production and marketing data. The maximum hours attributed by ADL to the domestic form's section were: four for clerical, 16 for technical, and four for managerial. Yet, any estimate of the maximum hours for the foreign form's section must exceed these hours to reflect the additional information required under case 2. ICF estimated that this additional information requires an approximate 50 percent increase over the labor necessary for completing the comparable section of the domestic form. Thus, maximum hours for this section were increased by 50 percent over those for the domestic form.

EXHIBIT 4-3 (continued)

COSTS OF SUBMISSION OF INFORMATION

Option 2. Revised Information Requests of Foreign Manufacturers/Suppliers.

Sections of Forms Required Under This Option	Information Category	Comparable Section of Proposed Domestic Manufacturer Form (Source of Required Hours)	Hours Clerical ($10/hour)	Hours Technical ($25/hour)	Hours Managerial ($50/hour)	Cost (in dollars)
Revised Form: I.A minus items 4 and 5	General Information	Revised Domestic Form: I.A	0 - 1[c]	0 - 0	1 - 8	50 - 410
Revised Form: I.B	Chemical Identity	Revised Domestic Form: I.B	0 - 2[c]	2 - 13	0 - 0	50 - 345
Revised Form: I.C	Generic Names	Revised Domestic Form: I.C	0 - 1[c]	0 - 4	0 - 1	0 - 175
January 10 Form: I.C minus items 3, 4(c), 5(a)(iii), 6, 7, and 8, plus Revised Form: I.D, item 2 only	Production and Marketing Data	January 10 Domestic Form: I.C minus items 3, 4(c), 5(a)(iii), 6, 7, and 8, plus Revised Domestic Form: I.D, item 2 only	1 - 2[c]	3 - 16[c]	1 - 3[d]	135 - 570
Revised Form: IV.A, IV.C, and IV.D	Federal Register Notice	Revised Domestic Form: Part IV	1 - 2	1 - 8	1 - 2	85 - 320
Revised Form: I.F	Risk Assesment	Revised Domestic Form: I.F	0 - 2[c]	0 - 16	0 - 2	0 - 520
January 10 Form: II.B and II.C	Risk Analysis, Structure/Activity Relationships	January 10 Domestic Form: I.B and II.C	20 - 40	20 - 120	15 - 30	1,450 - 4,900

Total Cost: $1,770 - 7,240

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[b] From "Regulatory Alternatives," EPA Working Paper, February 1980, pp. 38-39.

[c] ADL did not provide estimates of clerical hours for these sections. ICF estimated these hours by using ratios of clerical to professional hours. From ADL's time estimates for the reproposed domestic manufacturers form, the ratio of total minimum clerical hours to total minimum professional hours is 0.23, and the ratio of total maximum clerical hours to total maximum professional hours is 0.13. The minimum professional hours (technical and managerial) in each row of the table were multiplied by 0.23 to yield an estimate of the minimum clerical hours. These values were rounded to the nearest hour.

[d] The information required under the Production and Marketing Data category is information requested in various discrete items of the January 10 and revised forms. As a result, there are no ADL time estimates for this information. Rather, ADL estimated labor requirements for the larger categories that contain these discrete items. ICF estimated the labor requirements by considering each item's required labor as a fraction of ADL's labor estimations for the larger category containing that item. For the items in the January 10 foreign manufacturer/supplier form (section I.C minus items 3, 4(c), 5(a)(iii), and 6-8), ICF estimated two to eight technical and one to two managerial hours. For the reproposed form's item 2 of section I.D, ADL had provided an estimate for technical hours of one to eight, but did not provide an estimate for managerial hours other than a single estimate for the entire section. The managerial hours for this item were estimatd by ICF to be zero to one. Clerical hours for the Production and Marketing Data category were estimated using ratios of clerical to professional hours (see footnote c/).

EXHIBIT 4-3
(continued)

COSTS OF SUBMISSION OF INFORMATION

Option 3. Health and Environmental Effects Data: Request of Foreign Manufacturers/Suppliers to Complete Section III.B of the Reproposed Domestic Manufacturer Form

	Clerical	Technical	Managerial
Hours:	2 - 6[c]	8 - 40	2 - 8
Cost Per Hour:	$10	$25	$50
Cost:	$20 - 60	$200 - 1,000	100 - 400
		Total Cost:	$320 - 1,460

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[c] ADL did not provide estimates of clerical hours for these sections. ICF estimated these hours by using ratios of clerical to professional hours. From ADL's time estimates for the reproposed domestic manufacturers form, the ratio of total minimum clerical hours to total minimum professional hours is 0.23, and the ratio of total maximum clerical hours to total maximum professional hours is 0.13. The minimum professional hours (technical and managerial) in each row of the table were multiplied by 0.23 to yield an estimate of the minimum clerical hours. These values were rounded to the nearest hour.

Sources: Arthur D. Little, Inc., Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, prepared for the EPA Office of Toxic Substances, September 1979.

Arthur D. Little, Inc., Impact of TSCA Proposed Premanufacturing Notification Requirements, prepared for EPA Office of Planning and Evaluation, December 1978.

CHAPTER 5

EXPORTERS

This issue pertains to the manufacture in the U.S. of new chemicals for the sole purpose of export. The purpose of the information requested is to enable EPA to determine whether unreasonable risk is posed by these new chemicals during manufacture and transport in the U.S.

EXPORTER OPTIONS

Three alternatives evaluated by the contractor concerning new chemicals manufactured solely for export are the following:

> Option 1: Exporters are required to submit a notice form under section 5 of TSCA. The form would be similar to the exporters form in the October 16th reproposal, but would not include information about uses and exposures occurring outside the U.S.
>
> Option 2: Exporters would be exempt from section 5 authority but would be subject to reporting requirements under section 8(a) of TSCA. As defined by EPA, this option would require exporters to submit a notice form at least 90 days before commencing manufacture of a new chemical substance. The form again would be similar to the October 16th exporters form, excluding the section on uses and exposures outside the U.S. This option would also include a small business exemption for companies with an annual income under $1 million.
>
> Option 3: Exporters would be exempt from any reporting requirements for new chemicals manufactured solely for export.

Evaluation Framework

In this section, the direct costs to industry of each option are evaluated, using option 3 as a baseline from which to assess the other options. Option 3 exempts manufacturers of chemicals solely for export from any reporting requirements and therefore poses no costs to the industry.

The direct costs to the industry are seen as the following:

- Costs of Notice Submission, including out-of-pocket costs of filling out notice form, and the delay in introduction of new chemical; and

- Post-submission Costs, including costs, delay (5(c)), and uncertainty involved in possible supplementary reporting requirements, section 5(e) and 5(f) actions.

Exhibit 5-1 shows a matrix of the options and their relative costs. It is discussed more fully below.

EXHIBIT 5-1

COSTS TO INDUSTRY

	Option 1	Option 2	Option 3
Coverage	2	1	0
Costs of Submission	1	1	0
Potential Post-Submission Costs			
Supplementary Reporting	1	1	0
Uncertainty	1	0	0
Delay in introduction of chemicals (5(c) extension of Notice Period)	1	0	0
Sections 5(e) and 5(f) action	1	0	0
Action under other TSCA authority	1	1	1

For ordinal estimates, 0 = no cost, 1 = lowest cost, 2 = next lowest cost.

COVERAGE

The number of people affected by reporting requirements for chemicals manufactured solely for export varies for the different options. Under option 3, manufacturers would be entirely exempt from reporting these chemicals. Option 1 entails the widest coverage of exporters, differing from option 2 in that option 2 includes a small business exemption.

The small business exemption under option 2 would exempt exporters with total annual sales less than $1 million from reporting requirements. It is difficult to estimate precisely how much this provision would reduce coverage of exporters. (Data from the Census of Manufactures are too highly aggregated to permit an accurate assessment.) However, most small firms appear to rely heavily on close marketing relationships with their customers, so it is not likely they would be heavily involved in manufacture solely for export. The difference in coverage between options 1 and 2 is therefore not expected to be large.

It is difficult to estimate the size of the market for chemicals made solely for export. Most such chemicals would be specialty products and many would be custom made for particular customers. The reasons for manufacturing a new chemical solely for export can range from differences in U.S. and foreign technology to a foreign firm being the only known customer. Examples cited by companies include (1) different uses or applications for chemicals in Europe and the U.S., and (2) different performance standards or environmental and health standards for chemicals in the U.S. and some underdeveloped countries.

None of the companies contacted who manufacture chemicals solely for export operate in the second category. However, there may be companies that specialize in chemicals for foreign markets. In most firms, solely-for-export chemicals would not represent a large proportion of total business. Large chemical companies would likely manufacture a new chemical abroad if a major and sole foreign market were identified.

Costs to Exporters

Costs of Notice Submission. These costs, incurred by exporters under options 1 and 2, involve completing the required reporting form. The basis for the cost estimates was the ADL work on estimating the costs for preparation and submission of the October 16 domestic manufacturers form.[37] The minimum exporters form cost is the minimum domestic manufacturers form cost less than the minimum cost for section II-B (industrial sites controlled by others) and the minimum cost for section II-C (consumer and commercial user exposure). Because the minimum cost of II-B and II-C are both zero, the minimum exporter's form cost is estimated to be $1,200. The maximum exporter's cost, $8,100, is the maximum domestic manufacturers form cost plus the cost of completing section II-C.

Both option 1 and option 2 would require the same form to be used; the out-of-pocket costs of notice submission would therefore be equivalent. Likewise, under these two options, the forms would have to be submitted at least 90 days in advance of manufacture. Thus, any delays in the introduction of a new chemical due to this requirement would be equivalent for options 1 and 2.

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[37] Arthur D. Little, Inc. Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form (Cambridge, Mass.: September 1979), p. 38.

Post-Submission Costs. The primary difference between options 1 and 2 is the statutory authority covering exporters. Under option 1, exporters would be subject to section 5 regulations, including the possibilities of an extension of the notice period, regulation pending development of additional, not previously existing information (section 5(e) action), and regulation for protection against unreasonable risks (section 5(f) action). Under option 2 (and option 3), exporters would not be subject to actions under sections 5(e) and 5(f). However, under any of the three options, chemicals could be subject to action under sections 4, 6 and 7 of TSCA. Both options 1 and 2 would allow EPA to require supplementary reporting of information on a new chemical substance. The costs associated with this possibility would be the same under both options.

It should be noted that the post-submission costs to exporters are not fixed costs (such as the costs of notice submission). The magnitude of these costs would depend on the probability or frequency that an extension of the notice period or restrictive actions would be taken. Furthermore, the specific costs to the exporters involved in such restrictive actions would depend on a variety of factors, such as the cost of providing information requested by EPA, the extent to which an exporter appeals an Agency action, etc. These factors and the costs associated with them will vary on a case-by-case basis for each chemical. However, to the extent that action under section 5 is more likely than action under other sections of TSCA, the uncertainty over post-submission costs for a new chemical will be higher for exporters under option 1.

SUMMARY

Broadly considered, options 1 and 2 entail an equivalent cost to exporters. They differ in the authority EPA has to take action against new chemicals once a notice has been submitted. That difference would raise the cost to exporters under option 1 if such actions are taken and would increase uncertainty for exporters submitting notification. Both options 1 and 2 allow for the possibility that supplementary reporting will be required. Option 3 provides no information to EPA on new chemicals manufactured solely for export and imposes no costs on exporters.

CHAPTER 6

SUPPLEMENTAL REPORTING

In assessing a new chemical substance, EPA may require information other than that contained in the initial notice submission. In the following sections, we will:

- specify the options under consideration;
- specify the types of costs incurred by industry; and
- estimate the relative burden to industry of each type of cost.

SUPPLEMENTAL REPORTING OPTIONS

We have analyzed three alternatives to accomplish this task. They are:

- Option 1: January 10 proposal. Under option 1, EPA may require a submitter or processor of a chemical substance for which a notice has been submitted to report the following types of information:

  -- information which clarifies and supplements the information requested on the form;
  -- information concerning the benefits of substances for various uses and the availability of substitutes for those uses; and
  -- information concerning the economic consequences of any specified regulation under the Act.

  This information can be requested if the Agency believes that the information would be relevant to determine whether EPA should require the substance to be tested under section 4 of the Act, control the substance under section 5(e), 5(f), or 6(a), or follow-up on the substance under section 5(a)(2) or 8(a). EPA may also require the manufacturer or importer of an unknown reactant to report its identity or composition if the submitter demonstrates that he has attempted to obtain information concerning the identity of the reactant from the manufacturer or importer. In addition, the Agency may require any person who has possession of a health and safety study to submit it ". . . if the Agency believes that the study would assist in the evaluation of the health or environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance for which the Agency received a premanufacture notice".[38]

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[38] 44 Federal Register 2278.

The information that can be requested and the circumstances under which the information can be requested are quite broad.

- Option 2: October 16 proposal. The most important difference between option 1 and option 2 is that option 2 provides a more precise delineation of the information which may be required and the circumstances under which it may be required. In place of the broad definitions of the types of information which may be required, EPA provides a more detailed list of information grouped into the categories of manufacturing, processing or industrial use, distribution in commerce, disposal, and end use. The criteria which must be satisfied before information can be requested are also more specific. For example, to obtain information concerning the risk to human health and the environment resulting from environmental release, the Agency must find either that: (1) the substance may present a significant hazard to human health or the environment, and has a potential for release which would result in human or environmental exposure, or (2) data sufficient to determine toxicity are not available, and the substance has a potential for significant release resulting in human or environmental exposure. The types of health and safety studies and the circumstances under which their submission may be required, as well as the provisions which deal with obtaining information from manufacturers and importers of unknown chemicals, are no different from option 1. In addition, option 2 provides for an appeal to the Assistant Administrator or Deputy Assistant Administrator for Pesticides and Toxic Substances and limits the period during which information can be obtained to the review period; under option 1, the period during which supplemental reports could have been required was not specified.

- Option 3: Delete supplemental reporting rule. The Agency may still request information after the review period has ended under section 8(a) of the Act. If the agency has insufficient information to determine the risk of the chemical, it can regulate and obtain additional, not previously existing information about the chemical under section 5(e) (if the other requirements of that section are met).

Under each of the options, information could be provided voluntarily. Only if the information were not provided voluntarily would the formal supplemental reporting provisions be used.

EVALUATION FRAMEWORK

The costs of the supplemental reporting provisions to the chemical industry depend on the regulatory option which is chosen, the way in which EPA implements the regulations, the manner in which industry chooses to respond to the regulations, the nature of other section 5 rules, and the nature of the specific chemical market. The sensitivity of the costs to the discretionary behavior of both regulators and the regulated--behavior which is not controlled by the provisions of the Act--necessarily reduces the precision with which costs can be estimated.

The uncertainty about the future behavior of the industry and EPA means that we can only estimate the relative burden of each option to industry under each type of cost. The types of costs and the relative burdens attached to them are listed in Exhibit 6-1. The explanation for the entries in the matrix is given in the following section.

EXHIBIT 6-1

RELATIVE COSTS OF SUPPLEMENTAL REPORTING OPTIONS 1 THROUGH 3

Option:	1	2	3
Cost to Industry			
Out-of-Pocket Costs	3	2	a/
Delays	2	1	a/
Section 5(e) Action	1	1	a/
Uncertainty	3	2	1

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1 = lowest cost, 2 and 3 = next lowest costs, respectively.

a/These costs are heavily dependent on the actions of the submitters. Although we cannot be sure of the relative magnitude of each cost component under option 3, we do know that the total cost of all components will be lower under option 3 than any of the other options.

Out-of-Pocket Costs

The out-of-pocket costs include the administrative, clerical, and technical time needed to supply the information requested. This cost depends heavily on the amount of information that is requested and the frequency with which requests are made; EPA has considerable latitude to vary the cost to itself and the industry. There are upper limits placed on the cost, however. A person receiving a request need only submit information that is known or reasonably ascertainable; "we don't know" is an acceptable response to a request for information. The frequency is limited under each option to those cases which satisfy the criteria, but within such boundaries EPA can decide in each case whether or not to require information. The frequency with which EPA initiates a formal request is in turn dependent on the degree to which the industry voluntarily cooperates with requests for information.

Because the criteria for imposition of a supplemental reporting requirement under option 1 are broader than under option 2, there will be at least some cases in which information would not be available to EPA during the PMN period under option 2, but would be available during the PMN period under option 1. The appeal procedure under option 2 would further reduce the amount of information EPA could receive under option 2. The information delivered under option 3 will be less than under option 2, since there will be at least some cases in which the submitter will choose not to provide information that is requested. Therefore, the out-of-pocket costs will be greatest under option 1 and least under option 3. The magnitude of those costs is heavily dependent on the behavior of the industry and EPA. Therefore, the available information does not allow us to estimate the dollar amounts.

Delay in the Introduction of New Chemicals

A common complaint from industry as expressed in the public comments on previous proposals is that the notification process will result in delays in the introduction of new chemicals. Delays are costly to chemical producers and could result in a decline in the number of new chemicals introduced.[39] The possible sources of delay under the supplemental reporting provisions are:

- An extension of the notice period in order to allow more time to obtain supplemental information. This should be relatively insignificant since in most cases supplemental reporting will be associated with chemicals under detailed review and for which the notice period will probably have already been extended.[40]

- An extension of the notice period in order to allow more time to evaluate the information obtained from supplemental reporting. This should also be a minor problem, again because of the association between supplemental reporting and detailed review.

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[39] Comments of the Manufacturing Chemists Association on EPA Proposed Regulations for Premanufacture Notification Under Section 5 of TSCA, March 26, 1979, pp. 154-5.

[40] 44 Federal Register 59765 (October 16, 1979). EPA anticipates that it will be able to decide that most chemicals require no further regulation on the basis of the information provided in the notice and a literature search conducted by EPA staff.

As noted in the previous section, there will be less supplemental information obtained by EPA under option 2 than under option 1. Therefore, there will be fewer delays and less cost of delay under option 2; however, the differences between the two options should be minimal. The relative extent of delay under option 3, compared to options 1 and 2, is quite dependent on industry behavior. Therefore, we cannot estimate the extent and cost of delay.

Restrictions Under Section 5(e)

Under option 3, the refusal by firms to provide information voluntarily may result in restrictions being placed on use of the chemical until such information is provided under section 5(e) of the Act. These restrictions may result in losses of income and profits, and a reduction in chemical innovation, and should be considered therefore as costs to industry.

The cost to industry of section 5(e) restrictions may be great, but it is important to understand that section 5(e) actions will occur in the absence of any supplemental reporting rules. Therefore, any cost of actions taken under section 5(e) should not be attributed to the supplemental reporting provisions, but to the section as a whole.

Uncertainty About EPA's Implementation of Supplemental Reporting

In addition to the costs which may be imposed on the industry because of EPA's implementation of whatever option is eventually chosen, the uncertainty about how EPA will implement that option will itself impose costs on the industry. Because of EPA's wide degree of latitude under options 1 and 2, industry may take a considerable period of time to learn how the Agency will behave. In so doing, industry may take actions that may result in unnecessary costs and delays. Costs which are incurred as a result of such uncertainty are properly attributable to the regulations.

The major difference between option 1 and option 2 lies in this component of industry cost--uncertainty regarding EPA's implementation of the rules. Option 2 more precisely defines the information to be requested and the circumstances under which it will be requested than does option 1 under different circumstances. This increased specificity should make the cost of uncertainty under option 2 less than under option 1.

The difference between option 3, on the one hand, and options 1 and 2, on the other, lies in the ability of the submitter under option 3 to refuse requests for supplemental information. Because of this ability, the submitter must incur lower expected costs under option 3 than under the other options. The submitter can guarantee he does no worse under option 3 by acceding to all requests for information. But if the submitter believes that the expected costs of supplying a piece of information are greater than the expected costs of not providing the information (e.g., the possibility of restrictions under 5(f), the costs of delays), the submitter will, of course, choose to withhold the information. Therefore, under option 3,the expected costs to industry are lower than under the other options.[41] In effect, option 3 gives the submitter greater control over its own fate and causes less uncertainty about EPA's behavior than do options 1 and 2.[42]

SUMMARY

In comparing options 1 and 2, we find the costs of option 2 to industry are the lowest. Compared to option 1, option 2 reduces the uncertainty for industry, and will allow somewhat less information to be acquired by EPA, resulting in less delay and lower out-of-pocket costs. Both options 1 and 2 are more costly than option 3. Under the first two options, the Agency can require submitters to provide certain kinds of information, while under option 3, submitters may refuse requests for information. Therefore, the submitter must incur lower expected costs under option 3 than under the other options.

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[41] Even though expected costs are lower under option 3, actual costs may be greater. In the absence of information, the submitter's predictions about EPA's actions may be quite poor, as may his predictions of the cost of providing information. The submitter's actual, as opposed to expected, costs under option 3 will be lower only if his predictions are unbiased estimators of the actual outcome.

[42] This same analysis applies to the appeal procedure which is available under option 2 but not under option 1. The submitter will incur costs in making the appeal unless his expected benefits exceed his expected costs. Therefore, adding an appeal procedure provides a net benefit to submitters.

CHAPTER 7

INSUFFICIENT SUBMISSIONS

Section 5 of the Toxic Substance Control Act (TSCA) requires that a notice contain certain information. If submissions do not contain this information, EPA would inform the submitter of the deficiencies and provide the mechanism by which the submitter can correct the deficiencies.

In the following sections we:

- discuss the options under consideration;
- specify the types of costs incurred by industry; and
- estimate the relative burden to industry of each type of cost.

INSUFFICIENT SUBMISSION OPTIONS

We have analyzed four alternatives to accomplish this task. They are:

- Option 1: The January 10 proposal. The proposal divides deficiencies into major and minor categories. In the case of a major deficiency, the notice is invalid and the notice period does not start. The 90-day review period begins after the deficiency has been corrected. In the case of a minor deficiency, the notice period is suspended (the notice period clock stops running) until the deficiency is corrected. If the deficiency is not corrected within 30 days of the notice of deficiency, the notice may be declared invalid. The notice can be declared invalid at any time during the notice review period, although findings of minor deficiencies can only be made during the first 30 days. If EPA discovers at any time, even after the expiration of the notice period, that a submission includes intentionally false or misleading statements, EPA may find that the notice was invalid from the time of its initial submission. In addition, any production following such a submission is in violation of the Act. There are no procedures for appeal of agency decisions.
- Option 2: Addition of Appeal Procedures. Under this option, a submission containing a major deficiency is an incomplete submission. If the submission is incomplete, the notice period clock does not begin to run until the deficiency has been corrected.

  Unlike option 1, the submitter can appeal any finding that a submission is incomplete (within 10 days of notification of the finding), and the Agency may determine the submission is incomplete only within 30 days of receipt of the notice. The criteria for determining that a submission is incomplete are narrower than the grounds for determining major deficiencies listed under option 1. (See Exhibit 7-1). If the agency finds an error, the agency asks the submitter to correct the deficiency, but does not suspend the clock.

If EPA discovers at any time during the notification period that the submission includes intentionally false or misleading statements, the Agency may find that a notice was never submitted and the submitter is in violation of the Act. After the notification period, the Agency would prosecute intentionally false notices under federal laws concerning false and misleading information rather than TSCA.

- Option 3: Deletion of insufficient submission provisions from the rules. EPA could still find a submission to be insufficient to meet the statutory requirements, but such findings would be made on a case-by-case basis; there would be no general rule delineating the deficiencies. Under this option EPA would handle errors in much the same way as under option 2.
- Option 4: No insufficient notice provisions. Unlike option 3, in this case EPA would not reject submissions. EPA would obtain additional information by attempting to persuade the submitter to voluntarily provide it, by requesting further information under the supplemental reporting provisions, and/or by regulating the substance under section 5(e) of the Act. These actions may require an extension of the notice period.

EVALUATION FRAMEWORK

We will discuss, in turn, each of the costs to industry. The direct costs to industry are the following:

- Delay in the Introduction of New Chemicals;
- Restrictive Actions Under Section 5(e);
- Out-of-pocket Cost; and
- Uncertainty.

We will quantify costs to the extent permitted by the limited information on record. However, because the magnitude of each type of cost will vary depending on the behavior of submitters and EPA, the nature of other section 5 rules, and the nature of specific chemical markets, it is not reasonable to specify precise burdens attributable to the insufficient submission provisions.

EXHIBIT 7-1

CRITERIA FOR FINDING SUBMISSIONS TO BE INSUFFICIENT

Option 1	Common	Option 2
	Failure to sign the notice form.	
	Failure by an importer to comply with the procedures for obtaining information from foreign manufacturers or suppliers, in accordance with Section 720.21(c).	
	Failure to provide any information requested on the form or indicate that it is not known or reasonbly ascertainable.	
	Failure to provide any information required by Sections 5(d)(1)(B) and (C) of the Act, in accordance with Section 720.23.	
	Failure of a notice to include the test data or other information which the submitter is required to submit pursuant to a rule promulgated under Section 4 of the Act.	
	Failure to include the specific chemical identity of the substance for which the notice is submitted, unless it is impossible to do so in accordance with Section 720.20(f).	
	If EPA has listed a chemical substance under section 5(b)(4) of the Act, failure to submit data which the submitter believes show that the chemical substance will not present an unreasonable risk of detriment to health or the environment.	

EXHIBIT 7-1
(continued)

CRITERIA FOR FINDING MAJOR DEFICIENCIES

Option 1	Common	Option 2
Failure to remedy any deficiency for which EPA issued a request for correction under paragraph (a) of this section, within 30 days following a person's receipt of the request.		Failure to use appropriate notice form.
Submittal of intentionally false or misleading responses to questions on the form.		
Except as specifically authorized by Sections 720.10(a)(3) and (b)(2), submittal of a notice by someone other than either the person who intends to manufacture or import the chemical substance, or his designated agent.		
Failure to comply with the procedures for obtaining information from other persons, in accordance with 720.20(e), or to certify that the procedures have been complied with.		

Source: 44 Federal Register 2272-3 (January 10, 1979); guidance received from EPA.

It is reasonable, however, to specify relative burdens of each option to industry under each type of cost. The result will be a matrix of options and costs which are shown in Exhibit 7-2.

EXHIBIT 7-2

RELATIVE COSTS OF INSUFFICIENT SUBMISSION OPTIONS 1-4

Option	1	2	3	4
Cost to Industry				
Delays	2[a]	2[a]	2	2
Section 5(c) Action	1	1	1	2
Out-of-Pocket Costs	2	2	2	2
Uncertainty	1-2	1	4	1

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1 = Negligible
2 = Low
3 = Medium
4 = High

[a] The cost of option 2 should be less than the cost of option 1, even though both are low.

Delay in the Introduction of New Chemicals

The most important of the costs to industry with respect to this issue is the delay between receipt of the section 5 notice by EPA and the time at which the submitter can manufacture or import the substance. Chemical industry spokesmen have stated that delays in the introduction of new chemicals will be costly to the producers because the competitive advantage of new chemicals will be reduced. The result will be a reduction in the number of new chemicals introduced, which reduces the income and profits flowing to those companies whose new chemicals are not introduced.[43] Delays may result if the clock is stopped under the first three options, if the notice period is extended, or if supplemental reporting or section 5(e) actions are pursued under option 4.

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[43] Comments of the Manufacturing Chemists Association on EPA Proposed Regulations for Premanufacture Notification Under Section 5 of TSCA, March 26, 1979, p. 163.

If new chemicals are not introduced, individual firms and society as a whole may be harmed. But there may well be little or no cost to the industry as a whole. Individual firms whose products are not introduced because of delays in the section 5 notice process will lose income and profits, but income will flow to the producers of the products that would have been displaced by the new chemicals. Therefore, the chemical industry as a whole would suffer lost sales only when a foregone new chemical would have opened a new market for chemicals or when the foregone chemical would be replaced by imports. However, to the extent that the new chemical would increase efficiency and productivity in the chemical industry, its delay would indirectly hurt the industry.

Options 1 and 2 differ in the way that they treat errors. Under option 1, the notice period clock remains stopped until errors are corrected, while under option 2 the clock keeps running. Therefore, delays under option 1 are likely to be greater than under option 2. The extent of the delays should not be great in most cases--perhaps as little as two weeks--depending on how quickly firms respond to requests for corrections.

The criteria for not accepting a submission are somewhat different under options 1 and 2. Exhibit 1 shows the criteria for option 1 and option 2. Under option 2, eight major deficiencies are listed, seven of which are common to option 1. The only one that is not listed under option 1 is failure to use the notice form. Eleven major deficiencies are listed under option 1--the seven that are common to option 2 plus four others. Those four are failure to contact customers, failure to remedy an error (which does not apply under option 2), submission of intentionally false or misleading responses (which is covered in another part of option 2), and submission of a notice by someone other than the manufacturer or importer. The conditions under which a submission is incomplete are roughly the same under options 1 and 2, except that option 2 criteria are somewhat less extensive. Therefore, more submissions may be found incomplete under option 1 than under option 2.

Option 2 includes two other elements that are missing from option 1: an appeal process and the limitation of findings of major deficiencies to the first thirty days after the submission is received. The appeal process should result in a decrease in the cost of delays to industry, since it would only be used when the submitter felt the expected benefits of a successful appeal would exceed the additional delay resulting from the appeal process. The thirty day limitation may also reduce the number of rejections of submissions.

It is difficult to compare the extent of delays under option 3 to any of the other options, because EPA's latitude under option 3 is so large. Option 3 contains no guidelines on what fails to constitute a notice and no statement of the procedures EPA will follow in attempting to obtain information. The extent of delays under option 3 also depends on the willingness of the industry to correct deficiencies identified by EPA.

The possibility of delays under option 4 is also depends on the behavior of the industry. If option 4 is adopted and industry is willing to correct deficiencies voluntarily, there will be little delay. If industry does not respond, however, EPA could extend the notice period, request further information under the supplemental reporting provisions, or, if appropriate, regulate the substance under section 5(e) of the Act pending development and submission to the Agency of sufficient data to evaluate the substance's effects. A low level of voluntary cooperation on the part of the industry could lead to much greater delay under option 4 than under any other option. If delays are as costly as claimed by industry in public comments received on previous proposals, we could expect a relatively high degree of voluntary compliance under option 4.

As can be seen under all the options, the extent of delay depends greatly on the actions of chemical firms. If chemical firms are willing to correct deficiencies quickly, there should be little delay under any of the options. The extent of delays also depends, to a lesser extent, on the uncertain actions of EPA. Because delays in the introduction of new chemicals depend on the future behavior of EPA and the industry, any cost estimate will be highly uncertain. Assuming that submitters generally make good faith efforts to submit complete notices, the delays should be short and their costs low under all options. In addition, option 2 should produce fewer delays than option 1.

Restrictive Actions Under Section 5(e)

Under option 4, EPA may try to persuade submitters to voluntarily provide information, or EPA may use the supplemental reporting provisions to obtain information. If neither of these actions is successful in obtaining corrections, EPA may regulate the substance under section 5(e) of the Act pending development of information, provided the requirements for action under 5(e) are met.[44] Restrictions placed on the chemical under section 5(e) may reduce or eliminate the market for the substance or increase the manufacturer's cost of production. Note that imposing 5(e) restrictions can be taken for reasons other than the existence of an insufficient submission, but we deal here only with the 5(e) actions taken to correct insufficiencies.

Actions taken under section 5(e) to correct deficiencies in the notices occur only under option 4. Because the frequency of 5(e) actions is heavily dependent on the actions of EPA and the chemical industry, it is difficult to estimate the frequency with which 5(e) actions would be undertaken for this purpose. The cost to industry of each action taken could be significant. But if we assume that chemical firms generally make good faith efforts to provide complete submissions, the total costs of 5(e) actions in response to insufficient submissions should be low.

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[44] EPA may take action under section 5(e) if the Administrator determines that the information available is insufficient to permit a reasoned evaluation of the new chemical, and either (1) the manufacture, processing, distribution in commerce, use, or disposal of the substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment; or (2) the new chemical will be produced in substantial quantities, and either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the chemical.

Out-of-Pocket Costs

Industry will incur out-of-pocket costs to correct deficiencies under all options. Again, the cost of correcting deficiencies depends to a large extent on the behavior of the industry. Assuming that chemical firms generally make good faith efforts to provide complete submissions, the out-of-pocket costs should be small for all options.

Uncertainty

In addition to the costs incurred as a result of actions taken under these provisions, industry may also incur costs as a result of uncertainty about how EPA will implement the rules. Because of this uncertainty, firms may take unnecessary actions or fail to take necessary actions; they may devote too many or too few resources to the notice process. Some uncertainty is inevitable no matter which option is eventually chosen, since no set of rules can completely specify a future set of contingent actions. But a different degree of uncertainty is associated with each option.

Option 3 contains the most uncertainty for industry, since no criteria for identifying deficiencies is given. There is, furthermore, a great range of action open to EPA to request or require additional information. Much less uncertainty is associated with option 1, which provides some description of the criteria for identifying major deficiencies as well as a clear statement about the actions EPA can take in response to a deficiency. Least uncertain is option 2 which clearly delineates responses to an inadequate submission. Option 2 also lists the omissions which make a submission inadequate. In addition, option 2 provides that submissions must be determined to be insufficient within 30 days after the receipt of the material. We estimate that the cost of uncertainty is low for option 2, low to medium for option 1, and high for option 3.

Option 4 provides the least uncertainty to the submitter, since it gives the submitter the ability to refuse requests for information. Because the submitter has more control over the notice under option 4 than under the other options, its uncertainty must be less under option 4 than under the other options. The submitter can guarantee he does no worse under option 4 than under the other options by simply acceding to all requests for correction of insufficiencies. But if the submitter believes that the expected costs of supplying a piece of information are greater than the expected costs of not providing the information (e.g., the possibility of restrictions under section 5(e)), a rational submitter will choose to withhold the information. Therefore, under option 4, the expected costs to industry are lower than under the other options.[45]

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[45] Even though expected costs are lower under option 4, actual costs may be greater. In the absence of information, the submitter's predictions about (1) EPA's actions, (2) the cost of those actions, and (3) the cost of providing information may be quite poor. The submitter's actual, as opposed to expected, costs under option 3 will be lower only if his predictions are unbiased estimators of the actual outcome.

SUMMARY

As stated above, option 4 must be the least costly of all the options because of the discretion it allows the submitter. The differences among the other three options (as well as the magnitude of the difference between option 4 and the other options) are heavily dependent on the behavior of industry. The major differences among option 1, 2, and 3 lie in the cost of uncertainty. Option 3 has an uncertainty cost that is much higher than option 2. Option 2 has lower costs of uncertainty than option 1.

CHAPTER 8

PROCESSOR REPORTING

INTRODUCTION

EPA recently proposed a processor reporting rule to supplement the section 5 rules proposed on January 10 and October 16, 1979. The purpose of this analysis is to assess the potential economic impact of the proposed processor rule and its alternatives.

Because many of the costs of processor reporting do not easily lend themselves to quantification, the major outcome of this analysis is a ranking of options by expected economic costs to industry.

The analysis incorporates previous cost estimates by Arthur D. Little, Inc., for preparing and filing section 5 and "minimum guidance" notices. ICF estimates of the cost of submitting section 8 notices are also cited where appropriate. (See table at end of Introduction.)

Background information on the proposed rule and alternatives was obtained from EPA draft documents on processor reporting and communications with EPA personnel.

This analysis is organized in five sections. The first section provides background information on the proposed processor rule and states the scope of this analysis. Section 2 provides some information on the extent of processor reporting impacts, e.g., how many and what types of processors are likely to be affected by the proposed rule. Section 3 describes the options, and section 4 distills unique features from each option.

The analysis of economic costs begins in section 5 with the identification of major costs to industry and an assessment of the relative magnitude of such costs. The options are then ranked in terms of the following costs:

Out-of-pocket expenditures
Time delays
Disclosure of information
Risk of adverse determination
Number of persons covered

This analysis is designed to assist EPA in making optimal decisions on processor reporting by constructing an economic framework from which to evaluate the proposed rule and its alternatives.

ESTIMATED COSTS OF PREPARING AND FILING PROCESSOR NOTICES

Alternative Notices			
Section 5 Notice	$1,155	to	$8,925[a]
Section 8 Notice	724	to	4,450[b]
Minimum Guidance	1,011	to	7,486[c]
January 10 Notice	3,700	to	42,000[d]

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[a] Arthur D. Little, Inc., Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, September 1979.

[b] See Appendix A in Appendix-Volume I.

[c] ICF Incorporated, Estimated Cost of Compliance with the Minimum Guidance Option, April 1980.

[d] Arthur D. Little, Inc., Impact of TSCA Proposed Premanufacturing Notification Requirements, (Cambridge, Mass.: December 1978)

OVERVIEW

Background

The processor reporting rule only applies to certain, so-called "exempt," chemicals. It is therefore necessary to begin analyzing the rule by identifying which chemicals are affected by the rule. Section 3(2)(B) of the Toxic Substances Control Act excludes the following substances from coverage by the Act, as they are not chemical substances:

- any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide,
- tobacco or any tobacco product,
- any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),
- any article (e.g., firearms) the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue code of 1954 (determined without regard to any exemptions from such tax provided by Section 4182 or 4221 or any other provision of such code), and
- any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device.

Certain chemical substances are also exempted from section 5 review. Specifically, section 5(h)(1) authorizes the EPA Administrator to grant section 5 notice exemptions, upon application, for chemical substances manufactured or processed for test marketing.

Section 5(h)(3) exempts chemical substances manufactured or processed only in small quantities solely for the purposes of scientific experimentation or analysis, or for the purposes of chemical research on or analysis of the substances or another substance, including research or analysis for the development of a product (R&D).

In addition, section 5(i) of TSCA defines "manufacture and process" to mean manufacturing or processing for commercial purposes. Thus, section 5 reporting applies to chemicals manufactured or processed for commercial purposes. The January 10 proposal on premanufacture notification defines by-products as substances manufactured without a separate commercial purpose. Therefore, by-products are exempt from section 5 reporting.

On December 23, 1977, EPA promulgated regulations that allowed the reporting of chemical substances for the TSCA Inventory. The rules also allowed reporting for chemical substances manufactured, imported, or processed for a commercial purpose since January 1, 1975. Therefore, according to these rules, chemical substances manufactured or imported only before January 1, 1975 and not processed after that date and reported, would not be added to the Inventory. Although the Inventory was initially set up to comply with sections 8(a) and (b) of TSCA, it served other important purposes. In particular, chemical substances not on the Inventory after a certain date were to be considered "new" chemicals for the purposes of section 5 reporting.

In summary, the following chemical substances are covered by the proposed rule under certain conditions:

- those not within the TSCA definition of "chemical substances";
- those manufactured for test-marketing;
- those manufactured for research and development;
- those byproducts manufactured without a separate commercial purpose; and
- those manufactured only before January 1, 1975 and not processed and reported after that date.

The Need for a Processor Reporting Rule

The chemicals described above may be processed for a TSCA nonexempt commercial purpose. "Process" is defined in TSCA as the "preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce--(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (B) as part of an article containing the chemical substance or mixture." Reporting is not now required for the processing of an exempt, non-inventoried chemical for a nonexempt commercial purpose. Therefore, exempt substances processed for such a purpose would enter commerce without having been reviewed.

The rule would modify a subsection of the January 10 proposed regulation. According to this subsection, persons who intend only to process a new chemical substance for commercial purposes are not subject to premanufacture notification requirements (Subpart B, section 720.11 (b)).

Examples of Gaps Covered by Processor Reporting Rule

The processor reporting rule is designed to close a gap in EPA's regulatory scheme. The following serve as examples of instances when the processor rule would apply.

- Chemicals Not Within Scope of TSCA Definition of "Chemical Substance": A substance may not be on the TSCA Inventory because it is manufactured solely for a non-TSCA use. A processor wants to process the substance for a nonexempt commercial purpose, say as a plasticizer. Processing the substance creates a significant new use and changes the type, form, or duration of exposure. Although the substance may have previously fallen under a regulatory authority other than TSCA, the processor rule would require that the substance be reported and reviewed before it is added to the Inventory and possibly used for any TSCA purpose.

- By-products: The production of a chemical results in a by-product which is of no commercial value to the manufacturer. However, a processor may later find it profitable to process and distribute the by-product in commerce. Under the January 10 proposal, no section 5 notice is required because the by-product is exempt and because processors are not subject to premanufacture notification requirements. The processor rule would allow EPA to review the by-product for toxic effects before it is processed for commercial activity.

- Research and Development Substances: A new substance is manufactured for research and development. No section 5 notice is required. A processor other than the manufacturer may want to process and sell the R&D substance for a nonexempt purpose. No section 5 notice is required because the January 10 proposal does not require section 5 notices from persons who intend only to process a new chemical substance for commercial purposes. The processor rule would allow EPA to review changes in exposure to the chemical substance.

- Test-marketed Substances: A new substance is manufactured under a test-marketing exemption. The substance shows no sign of profitability in its test-marketed form. However, a person other than the manufacturer recognizes an economic benefit in processing the substance. Again, no section 5 notice is required under the January 10 proposal. The processor rule would require submission of a notice prior to processing.

Scope of Analysis

The processor rule may impose certain costs on industry. Our task is to identify these possible costs and assess the extent and magnitude of their impact.

We approach this task first by specifying the processor reporting options and distilling from each option unique features related to coverage, reporting requirements, enforcement, and disclosure. Next, we examine the expected economic costs to industry of processor reporting. In order to assess the extent of these costs, we make several assumptions based on information provided by EPA. Finally, the alternatives are ranked according to their expected impact.

EXTENT OF IMPACTS

Processors

Chemical industry processors who will now be subject to section 5 requirements include manufacturers and importers who process substances and "separate" processors who do not manufacture or impact the exempt chemical substances.

The precise number of processors falling in these categories is not available. However, according to a report prepared for EPA,[46] over 50 percent of the chemical firms in the United States only process or formulate chemicals and do not manufacture them, i.e., they are "separate" processors. Assuming there are 7,000 chemical firms (excluding drug companies), at least 3,500 separate processors may be affected by a processor reporting rule.

It is important to know not only how many processors will be affected by the rule, but also who these processors are. How they fill out the notice form will reflect their knowledge of the chemical and this may in some way affect EPA's action on a notice as well as the kinds of assumptions the Agency makes about a particular notice. EPA has solicited comments from processors on the proposed rule. When this information becomes available, it will be possible to determine the number of processors which will be affected. Financial characteristics of processors may also affect analysis of the impacts of a processor rule to the extent that a notice requirement may alter a processor's decision to commercialize an exempt substance for a TSCA purpose.

Substances

Another important part of the analysis is the number of notices expected to be submitted under the rule. How often are chemicals processed in such a manner as to require reporting under the rule? This question is related not only to industry costs, but also to the costs of administrative review of processor notices by EPA.

Estimates of the number of exempt chemical substances are not available. However, the following assumptions help to narrow the focus of the analysis:[47]

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[46] Arthur D. Little, Inc. Impact of TSCA Proposed Premanufacturing Notification Requirements (Cambridge, Mass.: December 1978), page II-2.

[47] Assumptions were obtained from Premanufacture Review Program; Proposed Processor Requirements, 45 FR 54642, August 15, 1980.

- Substances manufactured for foods, food additives, drugs, or cosmetics are not likely to be processed frequently for TSCA purposes due to their specialized applications and chemical formulas. The same is likely to be true for chemicals manufactured as source materials, special nuclear materials, or by-product materials as defined by the Atomic Energy Act of 1954.

- Substances manufactured for R&D and test marketing are likely to be processed more frequently for nonexempt commercial purposes than other types of exempt substances because they were manufactured for exploring nonexempt uses in the first place.

- Pesticide ingredients are likely to be processed for nonexempt commercial purposes. This assumption is based on the presence of inert and active pesticide ingredients on the TSCA Inventory.

Under these assumptions, greater emphasis may be placed on R&D chemicals, substances with test marketing exemptions, and pesticide ingredients. EPA provided the following information that may be valuable in setting constraints on the analysis:[48]

- Of 1,452 pesticide active ingredients, 688, or 47.4 percent are listed on the TSCA Inventory.

- Of 734 inert pesticide ingredients, 617, or 82.7 percent are on the Inventory.

- It is probable that not all of the pesticide ingredients reported for the Inventory were reported by processors. Some were manufactured or imported in a manner inconsistent with an exemption and thus were reported for the Inventory by manufacturers or importers.

- One thousand to 2,000 new R&D chemicals are manufactured each year. This range cannot serve as a lower bound on the number of R&D substances affected by the processor rule because not every new R&D chemical will be processed for a nonexempt commercial purpose. Secondly, this range cannot serve as an upper bound on the number of R&D substances affected each year because "old" R&D chemicals may also be processed for nonexempt commercial purposes. However, this range can serve as an upper bound on the number of new R&D substances potentially affected by the processor rule each year.

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[48] *Ibid*.

OPTIONS

Substances manufactured or imported for TSCA-exempt purposes may later be processed for TSCA commercial uses. Under the joint statutory authority of TSCA Sections 5(a)(1) and 5(a)(2), EPA has proposed to require any person who first processes an exempt, non-inventoried substance for a nonexempt purpose to submit a section 5 notice. The notice would be virtually identical to a premanufacture notice.

For purposes of analysis, the Agency specified the following alternatives to the proposed processor rule:

- January 10 Proposal--Manufacturer and importer reporting;
- no reporting for commercial processing of exempt substances;
- section 8 processor notification;
- processor rule as proposed, with exemption for one-time processing;
- combination of section 5 and section 8(a) notices; and
- minimum guidance notice.

Features of the proposed rule and its six alternatives are described in Sections 3.1 through 3.7.

Option 1--Proposed Processor Reporting Rule

At least 90 days before commencing first-time commercial processing for a TSCA purpose, the processor must ensure that a section 5 notice is submitted.

The prospective processor has three options for reporting. He may:

- submit the notice himself;
- persuade the manufacturer or importer to submit it; or
- submit the notice jointly with the manufacturer or importer.

In any event, the processor is responsible for ensuring that the substance in question completes a section 5 review prior to processing.

In addition to data required by the section 5 rules as proposed on January 10 and October 16, the processor must submit information concerning:

- the current source of the substance; and
- future sources of the substance.

Option 2--January 10 Proposal

Sections 720.10(a)(3) and (b)(2) of the January 10 proposal require section 5 notices from the manufacturer or importer if he distributes or uses R&D or test-marketing substances in a manner inconsistent with these exemptions. Separate processors would not be required to submit notices.

Option 3--No Reporting for Commercial Processing of Exempt Substances

There would be no reporting prior to the processing of a chemical substance for a nonexempt commercial purpose.

EPA could conceivably rely on the terms of TSCA Sections 5(a)(1)(A) and 15(2) to restrict the nonexempt processing of exempt substances.

Option 4--Section 8 Processor Notice

As an alternative to the processor reporting rule, EPA could require preprocessing notices under the authority of TSCA Section 8. Briefly, a section 8 rule could have the following features:

- does not apply to "small processors";
- allows a notice to be submitted less than 90 days before processing;
- may require fewer data than the October 16th proposed section 5 notice;
- does not result in the substance being added to the inventory (as considered here); and
- no section 5(e) or 5(f) action could occur during the review period.

With respect to the last feature, the Administrator could not issue proposed section 5 orders to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the substance in question, but could regulate the chemical under TSCA sections 4, 6, and 7.

Option 5--Processor Rule with Exemption for One-Time Processing

One-time processing applies to those exempt substances processed for use on a one-time or limited basis and processed only as an alternative to disposal of the substance. Option 5 incorporates this one-time processing exemption into the provisions of option 1. (This exemption could be incorporated into most of the options.)

Under option 5, EPA is considering limited section 8 reporting only for those substances that:

- were manufactured or imported in quantities over 500 pounds for R&D or test marketing; and
- are processed for a nonexempt commercial purpose in quantities over 500 pounds, solely as an alternative to disposal.

R&D and test-marketing substances processed for a nonexempt commercial purpose in quantities under 500 pounds, solely as an alternative to disposal could be processed without any section 5 or section 8 notification requirements.

Option 6--Combination of Section 5 and Section 8(a) Notices

Option 6 is a combination of options 1 and 4 and consists of two parts:

- section 5(a)(2) notice for substances of special concern; and
- section 8(a) notice for the remainder of exempt substances processed for nonexempt commercial purposes.

The section 5 rule would apply to specific chemical categories (selected by EPA) whose nonexempt commercial processing raises special concern about toxicity or exposure. The rule would establish which processors would report and when they would report.

Option 7--Minimum Guidance Section 5 Notification

This alternative would cover the same persons as the "rule" proposed in August 1980. It would require a 90-day advance notice and would provide minimum guidance on information requirements. The minimum guidance notice takes somewhat less time to complete than a section 5 notice as proposed in October. This statement is based on the Arthur D. Little and ICF estimates for the cost of submitting a section 5 notice[49] and the cost of submitting a notice under the minimum guidance option.[50] The former would range from $1,155 to $8,925 and the latter would range from $1,011 to $7,486.

Regulatory action under sections 5(e) and 5(f) could still be taken under option 7.

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[49] Arthur D. Little, Inc., Estimated Cost for Preparation and Submission of Reproposed Premanufacture Notice Form (Cambridge, Mass.: September 1979).

[50] ICF Incorporated, Estimated Cost of Compliance with the Minimum Guidance Option.

MAJOR DIFFERENCES AMONG ALTERNATIVES

Comparisons between processor notice options indicate three major areas of difference. They are:

- Coverage: Certain persons may be covered by one form of the processor rule and not by others. For example, separate processors do not submit notices under Option 2 (January 10 Proposal). However, the proposed rule (option 1) would require separate processors to submit section 5 notices.

- Reporting Requirements: Some alternatives request more information than others.

- Regulatory Authority: The options differ in terms of subsequent regulatory action. For example, under a section 8 rule, EPA could not regulate the production or distribution of an exempt substance that is processed for a nonexempt commercial purpose using section 5 authority. However, under the proposed rule, the Agency would regulate such a substance under TSCA Sections 5(e) and 5(f).

- Time: Some options require a notice to be submitted before a specified time period while other options allow submissions upon processing. This feature creates differences across options in terms of delays experienced by the processor before he is allowed to commence his operations. For example, the proposed processor reporting rule would represent at least a 90-day delay for the processor; the no reporting option, of course, means no delay, and the section 8 option could represent almost no time delay in processing a chemical substance.

In addition to these areas, certain options may have features that distinguish them in terms of implementation costs, confidentiality effects, risk of adverse determinations, etc.

The Appendix to this Part summarizes differences between options in terms of coverage, reporting requirements, risks of disclosure, and other factors.

ANALYSIS OF ECONOMIC COSTS

EPA is proposing the processor notice rule to ensure that exempt substances undergo Agency review prior to commercial processing for a nonexempt purpose. Without such a rule, persons could process for a TSCA commercial purpose an exempt substance which was not on the Inventory and which was never reviewed for toxic effects.

Although the January 10 proposal (720.11 Note) allows the manufacturer or importer to request that the processor "participate in the filing of the notice by providing information on uses and exposures, either to the manufacturer or importer, or directly to EPA," the proposal does not establish any mechanism for the processor to file a notice independent of the manufacturer or importer.

The purpose of this section is to identify the economic burdens that may accompany promulgation of a processor notice rule.

Industry Costs

The bulk of the economic costs of a processor rule will fall on industry in the form of out-of-pocket costs, time delays, risks of disclosing confidential business information, and risks of adverse determinations. This section deals with industry costs in four parts. The first describes the potential costs incurred by processors on a per-notice basis. The second part explains why costs differ among processors, and the third part summarizes the cost of a processor rule for the industry as a whole. In the fourth part of this section, the processor rule and its alternatives are ranked according to cost.

Per-Notice Costs. The per-notice cost to industry of filing a processor notice directly corresponds to the cost of filing a premanufacture notification as it applies to manufacturers and importers. Examples of possible industry costs include the following:

- Out-of-pocket expenditures: This category involves the direct cost of providing information. Out-of- pocket costs will vary from alternative to alternative, depending on the amount and type of information requested.

- Time Delays: Preparing and filing a processor notice and awaiting EPA review may cause significant delays in getting a processed substance out in commerce. The costs of such delays are clear. However, it is likely that the length of delay will vary from alternative to alternative.

- Disclosure: For various reasons, a processor may not want to disclose his intent to process a chemical substance. However, if a processor must contact the manufacturer or importer of a chemical substance for additional information to complete a notice, the processor risks disclosing his intent to process. The need to contact the manufacturer or importer may arise when the processor lacks complete information on the chemical identity, production process, production volume, or other data requested in a notice form.

  The risk of disclosing an intent to process may arise under any one of the alternatives, except the "no reporting" option.

- Risk of Adverse Determinations: Under the January 10 proposal, separate processors were not faced with EPA regulatory action. With the processor rule, exempt substances processed for a TSCA commercial purpose could be regulated under sections 5(e) and 5(f). This added risk represents a cost to industry because it may discourage processing and lead the industry to forego potential earnings on the processed substance.

Variables Influencing Notice Costs. According to a report by ADL,[51] the following company-related variables could affect the cost of filing a notice:

- company size;
- organizational structure (centralized vs. decentralized);
- existing information storage and retrieval methods;
- information availability;
- level of technical resources used to complete notice; and
- importance of claiming confidentiality.

In addition, the report cites the following chemical-substance-related variables that could influence notice costs:

- apparent toxicity of chemical substance;
- anticipated sales or profit potential;
- complexity of chemical production process; and
- complexity of chemical composition.

Because the behavior of these variables is unique to each situation that requires a section 5 notice, the cost of filing a notice is expected to be different for each substance.

Total Industry Cost. The total cost to industry of a processor notice rule is the sum of all per-notice costs incurred in a given period of time.

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[51] Arthur D. Little, Inc., Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form (Cambridge, Mass.: September 1979).

An important caveat arises in the calculation of total industry costs. That is, the number of notices attributable to the processor rule does not include notices that would have otherwise been submitted without the rule. This caveat is applicable on two occasions:

- when the processor is the same person as the manufacturer or importer of an R&D or test marketed substance, and knows prior to manufacture that he or another will process the substance for a nonexempt purpose; or

- when the processor is not the manufacturer or importer, but the manufacturer or importer of an exempt substance would have submitted a notice because he knew of an intent to process the substance for a nonexempt commercial purpose.

In the first instance, no new costs would be added by a processor rule. Using the January 10 proposal as the baseline for analysis, the manufacturer or importer of an R&D or test-marketed substance would file a notice under sections 720.10(a)(3) and (b)(2) because he would have had knowledge of an intent to use his exempt substance "in a manner inconsistent with the terms of the applicable exemption." With a processor rule, the same person (the importer or the manufacturer) would file a notice presumably at the same cost.

In the second instance, the processor is distinct from the manufacturer or importer. However, the manufacturer or importer may still know of the processor's intent to process an exempt R&D or test-marketed chemical for a nonexempt purpose and would have submitted a notice under Sections 720.10(a)(3) and (b)(2). With a processor rule, the savings realized by the manufacturer or importer in a transfer of reporting responsibility would cancel the costs incurred by the separate processor, ceteris paribus, of submitting a notice. Thus, no new costs would be added by a processor rule in this case either.

Costs incurred by a processor in filing a section 5 notice would be directly attributable to the processor notice rule as long as a notice would not have been submitted by the manufacturer or importer in the absence of a processor rule (e.g., in the case where the manufacturer or importer did not have knowledge of an intent to process an exempt substance for a nonexempt purpose at the time of manufacture).

Ranking of Alternatives by Cost. Ranking the proposed processor rule and its alternatives by cost requires a few assumptions. The assumptions are:

- all notices are submitted by persons of identical salaries and technical expertise;

- all notices are submitted by processors of identical financial characteristics, including company size and organization;

- all processors have the same quantity and quality of information regarding the substance to be processed; and
- time delays, uncertainty, risks, etc., affect all processors equally.

Exhibit 8-1 presents the results of ranking all options by per-notice cost and by coverage. A "1" indicates the least costly alternative or least coverage. A higher rank indicates a more costly alternative or more extensive coverage. The ranking was based on information from a number of sources:

- ADL estimates in Impact of TSCA Proposed Premanufacturing Notification Requirements, December 1978.
- ADL estimates in Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, September 1979.
- Premanufacture Review Program; Proposed Processor Requirements, 45 FR 54642, August 15, 1980.
- ICF estimates in "Cost Estimates of Alternative Processor Notification Requirements" in Appendix A of Appendix-Volume 1.
- ICF estimates in "Estimated Cost of Compliance with the Minimum Guidance Option" in Appendix A of Appendix-Volume 1.

The ranks were established in the following manner:

- Out-of-Pocket Expenditures

  Option 3 (no reporting for commercial processing) and case 2 (January 10 proposal) of option 2 received the lowest rank for costs incurred in filing a notice. In fact, filing costs in both cases would be zero. Under the option of no reporting, a processor would not submit a notice. Under case 2 of the January proposal, the separate processor would not be required to submit a notice.

  Although a separate processor incurs zero cost under the January 10 proposal, a manufacturer who knows of an intent to process his substance for a nonexempt commercial purpose must submit a section 5 notice under the same (January 10) proposal. This case was included in the ranking to compare the out-of-pocket costs incurred by the manufacturer under the January proposal and by the separate processor under the proposed processor reporting rule. These options ranked among the costliest in terms of filling out a notice. ADL estimated $3,700 to $42,000 for a January 10 notice, and $1,155 to 8,925 for the proposed processor rule.

EXHIBIT 8-1

RANKING OF PROCESSOR NOTIFICATION OPTIONS BY COSTS TO INDUSTRY

Options	Costs Per Notice				
	Out-of-Pocket Expenditures	Time Delays	Disclosure	Risk of Adverse Determination	Coverage
1. Proposed Processor Notice Rule	4	4	4	2	5
2. January 10 Proposal[a]					
• Case 1[b]	5	4	3	2	2
• Case 2	1	1	1	1	1
3. No Reporting	1	1	1	1	1
4. Section 8 Notice	2	2	2	1	3
5. Processor Rule With Exemption					
• Section 5	4	4	4	2	4
• Section 8	2	2	2	1	4
6. Combined Section 5 and Section 8 Notice					
• Section 5	4	4	4	2	4
• Section 8	2	2	2	1	4
7. Minimum Guidance Notice	3	4	3 or 4	2	5

A "1" indicates the least costly alternative.

[a] Case 1 assumes the manufacturer has prior knowledge of an intent to process his substance for a nonexempt commercial purpose. Case 2 assumes that only the separate processor has knowledge of such an intent. All other options are ranked according to the Case 2 assumption.

[b] These costs are incurred by the manufacturer.

Option 4 (section 8 processor notice) received a rank of 2 because, as proposed here, less information is requested under the section 8 rule than under the section 5 rule (option 1) and less time would be required to complete the notice. According to ICF estimates, the cost of filing a section 8 notice under option 4 ranges from $724 to $4,450. This compares to ADL's estimates of $1,155 to $8,925 for completing a section 5 notice.

Out-of-pocket costs under options 5 (processor rule with exemption for one-time processing) and 6 (combination of section 5 and 8 notices) would be the same as under option 4 when a section 8 notice is required (i.e. from a one-time processor under option 5 and from a processor subject to section 8 review under option 6).

However, out-of-pocket costs under options 5 and 6 may be identical to out-of-pocket costs under the proposed rule when a section 5 notice is required (i.e. when the one-time exemption is inapplicable under option 5 and when a processor is subject to section 5 review under option 6).

The cost of submitting a notice with minimum guidance (ADL estimates of $1,011 to $7,486) is more than a section 8 notice ($724 to $4,450) and less than a section 5 notice ($1,155 to $8,925). Thus option 4 was ranked third costliest.

- Time Delays

Delays would be nonexistent under the no-reporting option and under case 2 of the January 10 proposal.[52]

Submitters of a section 8 notice will experience some delay, although it is expected that any delay will be shorter than under a section 5 notice for two reasons:

-- A section 8 notice may be submitted less than 90 days before processing, but a section 5 notice must be submitted at least 90 days prior to processing.

-- A section 8 notice requests less information than the proposed section 5 notice, thus the time required to complete the form is shorter.

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[52] Case 2 assumes that only the separate processor has knowledge of an intent to process for a nonexempt commercial purpose. Case 1 assumes that the manufacturer has knowledge of such an intent.

Therefore, option 3 and case 2 of option 2 were ranked as the least costly in terms of time delays. Option 4 was ranked as the next costly, followed by those options requiring a section 5 notice.

Because options 5 and 6 require either a section 5 or a section 8 notice, each was assigned two ranks. When the section 5 notice is submitted, delays will be the same as under option 1 and case 1 of the January 10 proposal. When the section 8 notice is submitted under option 5, delays will be somewhat longer than under option 4 for the reasons cited above. When the section 8 notice applies to option 6, delays would be identical to those under option 4.

- Disclosure

The risk of disclosing confidential business information is likely to be highest under the proposed processor rule. In addition to facing the possible disclosure of information as part of a notice submission, the separate processor is faced with another risk. That is, it may be necessary to contact the manufacturer in order to complete a notice, and the processor may not want the manufacturer to know of his processing intentions.

The manufacturer in case 1 of option 2 who knows that his substance will be processed for a nonexempt purpose must submit a section 5 notice and may incur some risk of disclosing information provided in the notice. However, because contact between a separate processor and the manufacturer is unnecessary (since no processor reporting is required), the risks of disclosure are less than under the proposed processor rule.

Under a minimum guidance option, manufacturer contact may be necessary. However, the processor need not submit as much information as was required in the section 5 notice proposed in October, so he risks the disclosure of less information. Taken together, these two conditions leave the minimum guidance option with a rank similar to that for options 1 or 2.

When section 5 notices must be submitted, options 5 and 6 rank high along with option 1 in terms of disclosure risks. When section 8 notices must be submitted, however, the options rank with option 4. Although manufacturer contact under option 4 may pose some risk of disclosure, it is unlikely that the risks will be as high as under option 1 and case 1 of option 2. Thus, the section 8 notice received the third highest rank.

Option 3 and case 2 of option 2 would pose no risk of disclosure.

- Risk of Adverse Determination

Upon reviewing a notice, EPA may determine that the intended activity described in the notice may present unreasonable risks. Under options where section 5 rules apply, EPA can take regulatory actions against the intended activity using the authorities of sections 5(e) and 5(f). Thus, risks of adverse determinations, i.e. regulatory action, are high under these options.

On the other hand, when no provision is made for a notice submission, EPA would have a more difficult time identifying activities that may present unreasonable risks, and processors would face lower risks of adverse determinations. This would be the case for the option of no reporting and for case 2 of option 1, where no notice would be filed. Thus, these options received ranks of 1, indicating least cost.

Submitters also face the risk of an adverse determination if they file incomplete submissions. That is, if EPA determines that a notice is incomplete, then the processor cannot begin his processing activities. While the risk of an adverse determination represents a cost in itself, the cost to a processor of an adverse determination is the foregone opportunity to process a substance for commercial purposes.

- Coverage

The total cost to industry of a processor reporting rule is a function not only of notice costs but of coverage. The more people covered by the rule, the higher the cost to industry, other things being equal.

The proposed processor rule requires that all those persons who process exempt chemicals not on the TSCA Inventory for nonexempt commercial purposes must ensure that section 5 notices are submitted. Coverage is widest under this option and also under the option requiring a notice submitted with minimum guidance.

Coverage is also broad under option 5, although one-time processors would be exempt from submitting section 5 notices. Therefore, option 5 ranks just under the proposed rule in terms of coverage.

Some uncertainty surrounds coverage under option 6. Small processors would be exempt from section 8 reporting. Thus, coverage is narrower than under option 1. However, some processors will be subject to section 5 reporting, and coverage under option 6 is greater than under option 4 which promises the third highest coverage.

Under case 1 of option 2, only a few processors are covered (i.e., the manufacturer/processor who will either process or know of an intent to process his substance for a nonexempt commercial purpose).

Under option 3 and case 2 of option 2, no processors are covered.

APPENDIX TO CHAPTER 8

DIFFERENCES AMONG OPTIONS

APPENDIX: DIFFERENCES AMONG OPTIONS

A.1 PROPOSED NOTICE RULE (7) VS. JANUARY 10 PROPOSAL (2)

Coverage:	Under option 2, the manufacturer or importer of an R&D or test-marketed substance is to submit a section 5 notice as proposed on January 10, 1979 if he distributes or uses the exempt substance in a manner inconsistent with the exemption. Option 2 does not permit separate processor reporting. Option 1 places reporting responsibility on the processors. Option 1 also deals with FIFRA, FFDCA, by-products and substances manufactured, only before January 1, 1975 and not processed after that date.
Reporting Requirements:	Under option 1, the processor submits a notice virtually identical to the manufacturer's October 16, 1979 proposed section 5 notice. The submitter is also required to identify sources of the substance, describe the manufacturing process, and estimate the amount of the substance to be processed.
Disclosure:	Although the processor is believed to have a good knowledge of his processing techniques and perhaps his end use of the substance, he may have a significantly less complete knowledge of its health and environmental effects and possibly the specific chemical identity. In these instances, the processor may find it necessary to contact the manufacturer for further information. This procedure raises the issue of confidentiality both for the processor and the manufacturer.
Other:	If the processor has a less complete knowledge of the substance, he may face a greater risk of follow-up action by EPA.

A.2 PROPOSED PROCESSOR NOTICE RULE (1) VS. NO REPORTING FOR COMMERCIAL PROCESSING OF EXEMPT SUBSTANCES (3)

Coverage:	Under option 1, the processor submits a notice. Under 3, no one, not even the manufacturer or importer who may be aware of an intended inconsistent use, submits a notice. In effect, option 3 permits all processed substances to enter commerce without EPA review.
Reporting Requirements:	Under option 3, no information is submitted to EPA for the commercial processing of exempt substances. Under the proposed rule, the processor submits a notice virtually identical to the domestic manufacturers' October 16, 1979 proposed section 5 notice.

Regulatory Authority:	EPA would have a difficult time enforcing TSCA under option 3. Without a processor rule, persons who process exempt substances for nonexempt commercial purposes could not be penalized for their activity. Yet, the intent of TSCA is to review such activity prior to commercial processing. Option 1 would satisfy this requirement.
Disclosure:	As described in A.1 of this appendix, the proposed rule raises the issue of confidentiality. With no reporting, the issue would not be raised.

A.3 PROPOSED PROCESSOR NOTICE RULE (1) VS. SECTION 8 PROCESSOR NOTICE (4)

Coverage:	Under 1, the processors submit a section 5 notice as proposed. Under 4, "small processors," are exempt from filing a section 8 notice.
Reporting Requirements:	Less information could be requested under option 4 than under option 1. Also a less-than-90-day advance notice could be permitted.
Regulatory Authority:	Whereas under 1, the Administrator could take action under sections 5(e) and 5(f) during the review period, under 4, the Administrator would be forced, in limited cases, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the substance under section 6 or 7.
Other:	As proposed, if a section 8 notice is filed for a processed substance, the substance would not be added to the TSCA inventory. This may or may not result in multiple submissions for the same processed substance.

A.4 PROPOSED PROCESSOR REPORTING RULE (1) VS. PROCESSOR RULE WITH EXEMPTION FOR ONE-TIME PROCESSING (5)

Coverage:	Coverage is identical, except that option 5 provides an exemption for one-time processors, i.e., persons qualifying for the exemption need not submit a section 5 notice but could be required to submit a section 8 notice, as proposed.
Other:	An exemption for one-time processing would allow the processor to recover all or part of his cost on the substance as an alternative to disposal. Without the exemption, the cost of filing a section 5 notice may induce the one-time processor to choose disposal.

A.5 PROPOSED PROCESSOR NOTICE RULE (1) VS. COMBINED SECTION 5 AND SECTION 8 NOTICE (6)

Coverage: Under 6, only selected chemicals would be subject to section 5 notification as proposed. The remainder of exempt substances would be subject to section 8 review. Under 1, no distinction is made and all exempt substances processed for a TSCA commercial purpose would undergo section 5 review.

EPA expects that under 6, a majority of the substances will undergo section 8 review, so the difference in coverage between options 1 and 6 is similar to the difference in coverage between options 1 and 4. In particular, "small processors" would be exempt from filing a notice.

Reporting Requirements: Again, because the majority of substances are likely to fall under section 8 review, the difference in reporting requirements between options 1 and 6 will be virtually identical to the difference between options 1 and 4. Under 6, however, two different types of notices would be submitted to the Agency for review.

Regulatory Authority: Refer to comparison between options 1 and 4 in Section A.3.

Other: Option 6 would impose a significant burden on the Agency to select which chemicals should be subject to section 5 review. These additional burdens hold true in all comparisons between option 6 and each of the other alternatives, but will not be repeated in other sections.

A.6 PROPOSED PROCESSOR NOTICE RULE (1) VS. MINIMUM GUIDANCE NOTICE (7)

Reporting: A notice submitted under the minimum guidance option would contain less information than a section 5 notice as proposed. This is based on a comparison between ADL cost estimates for a section 5 notice and a notice submitted under the minimum guidance option. ADL's results suggest that it would take less time to fill out a notice under the minimum guidance option than under the proposed section 5 rule. (See discussion of cost estimates in section 3.6 of main text.)

A.7 JANUARY 10 PROPOSAL (2) VS. NO REPORTING FOR COMMERCIAL PROCESSING OF EXEMPT SUBSTANCES (3)

Coverage: Although the January 10 proposal does not permit separate processors to submit section 5 notices, the Agency could resort to subsections 720.10(a)(3) and (b)(2) to regulate processed substances. In other words, EPA could require notices from manufacturers or importers who intend to use or distribute in commerce an R&D or test marketing substance in a manner inconsistent with the exemption. Under option 3, there would be no reporting for commercial processing of exempt substances by separate processors.

Reporting Requirements:	The January 10 proposal required information from manufacturers who either process their R&D or test-marketed substances for nonexempt commercial purposes or know their substances will be processed for nonexempt commercial purposes by someone else. Alternative 3 requires no information from processors, regardless of whether the processors are manufacturers or not.
Regulatory Authority:	EPA can regulate some processed substances under alternative 2 using sections 720.10(a)(3) and (b)(2). Under alternative 3, this authority would be removed.

A.8 JANUARY 10 PROPOSAL (2) VS. SECTION 8 PROCESSOR NOTICE (4)

Coverage:	Under 2, processed substances undergo section 5 review if they are R&D or test-marketing substances and are to be processed for a TSCA purpose by the manufacturer. Similarly, if the manufacturer knows that someone else will process the chemical for a TSCA purpose, it must undergo section 5 review. Under 4, substances commercialized by "small processors" are not subject to notification; other exempt substances processed for nonexempt commercial purposes would be subject to section 8 notification.
Reporting Requirement:	Less information would be reported under a section 8 rule than under the January 10 proposal.
Regulatory Authority:	Under the January 10 proposal, EPA can initiate section 5(e) or 5(f) action against R&D or test-marketed substances that are used or distributed in a manner inconsistent with the exemption if EPA determines that the processed substances would present an unreasonable risk.
Disclosure:	Because less information is reported under a section 8 rule, the risk of disclosing confidential business information or processing intentions is lower.

A.9 JANUARY 10 PROPOSAL (2) VS. PROCESSOR RULE WITH EXEMPTION FOR ONE-TIME PROCESSING (5)

Coverage:	Under 2, certain processed substances do not undergo section 5 review. Under option 5, they do, unless they are processed on a one-time basis.

Reporting Requirements: Under 2, no notice is filed for the processing of certain exempt substances. Under option 5, most processors file a notice virtually identical to the premanufacturing notice, in addition to information regarding sources of the substance. If the substance will be used on a limited basis, limited information must be filed.

Disclosure; Like the proposed processor notice rule, option 5 raises the issue of confidentiality in the event that the processor must contact the manufacturer or importer for additional information.

A.10 JANUARY 10 PROPOSAL (2) VS. COMBINED SECTION 5 AND SECTION 8 NOTICE (6)

Coverage: Under 2, certain processed substances do not undergo section 5 review. Under 6, selected substances would be subject to section 5 review and the remainder (perhaps a majority of the substances) would be subject to section 8 review.

Reporting Requirements: The January 10 proposal requires section 5 notices, as proposed, from manufacturers who process their R&D or test marketed substances for nonexempt commercial purposes, or who know their exempt substances will be processed for nonexempt commercial purposes by someone else. Under option 6, section 5 notices would also be required of certain processors. However, under option 6, some processors would be subject to less extensive section 8 reporting.

Regulatory Authority: Regulatory action allowed under the January 10 proposal and under option 6 is the same except when section 8 rules apply under option 6. When section 8 notices are submitted, EPA cannot take action under sections 5(e) or 5(f).

Disclosure: The risks of disclosure could be the same under both options when section 5 rules apply to option 6. Nevertheless, when section 8 notices are submitted under option 6, the risks are likely to be lower because less information would be reported and because manufacturer contact may be unnecessary.

A.11 JANUARY 10 PROPOSAL (2) VS. MINIMUM GUIDANCE OPTION (7)

Coverage: Option 2 does not permit processor reporting. Coverage under option 7 is the same as under the proposed processor rule, i.e., persons who process an exempt substance for a nonexempt commercial purpose must submit section 5 notices.

Reporting Requirements:	Under 2, the separate processor is not required to report. Under 7, the processor submits a notice identical to notices submitted with minimum guidance.
Disclosure:	Under both options, the processor risks the disclosure of information submitted to EPA. In addition, under option 7, the processor risks the disclosure of processing intentions that he may have wanted to keep confidential.

A.12 NO REPORTING FOR COMMERCIAL PROCESSING OF EXEMPT SUBSTANCES (3) VS. SECTION 8 PROCESSOR NOTICE (4)

Coverage:	Under 3, there would be no reporting for commercial processing. Under 4, exempt substances undergo section 8 review prior to commercial procesing for a nonexempt use.
Reporting Requirements:	The processor would file a limited section 8 notice under option 4 and no notice under option 3.
Disclosure:	Under a section 8 rule, processors risk the disclosure of whatever information is submitted to EPA. Under the option of no reporting, there would be no risks of disclosure.

A.13 NO REPORTING FOR COMMERCIAL PROCESSING OF EXEMPT SUBSTANCES (3) VS. PROCESSOR RULE WITH EXEMPTION FOR ONE-TIME PROCESSING (5)

Coverage:	Under 3, there would be no reporting for commercial processing. Under option 5, a processor submits a section 5 notice as proposed in October unless he qualifies for a one-time processing exemption.
Other Differences:	Same as differences described in A.2.

A.14 NO REPORTING FOR COMMERCIAL PROCESSING OF EXEMPT SUBSTANCES (3) VS. COMBINED SECTION 5 AND SECTION 8 NOTICE (6)

Coverage:	Under 3, commercial processors of exempt substances are not required to submit preprocessing notices. Under 6, some processors submit section 5 notices as proposed in October and the rest are subject to section 8 review.
Reporting Requirements:	There are no reporting requirements under 3. Under 6, most processors will be required to submit limited section 8 notices. A few will submit section 5 notices as proposed in October.
Regulatory Authority:	Option 3 provides no mechanism for regulating processed substances. Option 6, on the other hand, permits enforcement under TSCA sections 5(e) and 5(f) in a few cases.

Disclosure: Option 3 poses no risk of disclosing confidential business information. Option 6, however, would pose such a risk in the event that manufacturer or importer contact become necessary to satisfy the information requirements of the relevant notice form (i.e., section 5 or section 8 notice).

A.15 NO REPORTING FOR COMMERCIAL PROCESSING OF EXEMPT SUBSTANCES (3) VS. MINIMUM GUIDANCE OPTION (7)

Coverage: Under option 7, the processor submits a notice. Under 3, no processors submit notices for processed substances.

Reporting Requirements: Under 3, no information is submitted to Agency. However, under option 7, a processor will submit a notice that is consistent with the minimum guidance option.

Regulatory Authority: EPA may regulate substances under sections 5(e) and 5(f) of TSCA under 7. Under 3, these regulatory mechanisms would not be allowed.

Disclosure: Under 7, the processor risks disclosure of business information reported under the minimal guidance policy. In addition, he risks the disclosure of processing intentions should manufacturer contact becomme necessary in order to complete a notice.

A.16 SECTION 8 PROCESSOR NOTICE (4) VS. PROCESSOR RULE WITH EXEMPTION FOR ONE-TIME PROCESSING (5)

Coverage: Option 4 exempts "small processors" from filing a section 8 notice while option 5 exempts one-time processors from filing a section 5 notice as proposed.

Reporting Requirements: Under option 4, the section 8 notice may be filed less than 90 days before processing. Under option 5, the proposed section 5 notice must be filed at least 90 days prior to processing. As noted elsewhere, the section 8 notice requires much less information than the proposed section 5 notice.

Regulatory Authority: EPA could not regulate the manufacture, processing, distribution in commerce, use, or disposal of an exempt substance under a section 8 type rule. However, under a section 5 notice rule, the Agency could take action under sections 5(e) and 5(f) during the review period.

A.17 SECTION 8 PROCESSOR NOTICE (4) VS. COMBINED SECTION 5 AND SECTION 8 NOTICE (6)

Coverage: A section 8 rule would exempt "small processors" from reporting. Option 6 would also exempt "small processors".

In addition, selected processors would file section 5 notices.

Reporting Requirements: Except when the proposed section 5 must be submitted, option 6 would involve reporting the same information as alternative 4.

Regulatory Authority: If option 6 were selected, EPA would be authorized to regulate substances under sections 5(e) and 5(f) in a few cases.

A.18 SECTION 8 PROCESSOR NOTICE (4) VS. MINIMUM GUIDANCE OPTION (7)

Coverage: Section 8 rules may apply to all processors except those with "small business" status. The minimal guidance notice would cover all processors regardless of size.

Reporting Requirements: Based on ICF estimates of submitting a section 8 notice and ADL estimates of submitting a notice with minimum guidance, it will cost more to provide information under option 4. (See specific estimates in Section 5.1.4 of text.)

Regulatory Authority: TSCA sections 5(e) and 5(f) apply to the minimim guidance option but not to section 8 notices.

A.19 PROCESSOR RULE WITH EXEMPTION FOR ONE-TIME PROCESSING (5) VS. COMBINED SECTION 5 AND SECTION 8 NOTICE (6)

Coverage: Under option 5, only the one-time processor is exempt from reporting. All other processors would submit section 5 notices. Under option 6, a few processors would submit section 5 notices while the remainder would be subject to a section 8 rule which exempts "small processors".

Reporting Requirements: Except when a section 8 notice is submitted under option 6, reporting requirements would be the same for both alternatives. When a section 8 notice is submitted, the differences are similar to those between options 1 and 4. That is, less information would be required under a section 8 rule, and the processor may submit a notice less than 90 days before processing.

Regulatory Authority: Under option 6, EPA could take regulatory action against a substance in only a few instances, whereas under option 5 EPA would be able to regulate most substances during the review period.

Disclosure: Where the section 8 rule applied to option 5, the processor would risk disclosing less information than under a section 5 rule.

A.20 PROCESSOR RULE WITH EXEMPTION FOR ONE-TIME PROCESSING (5) VS. MINIMUM GUIDANCE OPTION (7)

Coverage:	Coverage under both options is almost identical except that under 5 an exemption is provided for persons who intend to process substances on a one-time basis as an alternative to disposal. Persons qualifying for an exemption will probably be required to submit section 8 notices.
Reporting Requirements:	A minimal guidance notice requires less time to complete than a section 5 notice as proposed in October. (See section 3.6 of text for relative cost estimates.) When the one-time exemption applies and a processor submits a section 8 notice, the minimum guidance option takes longer to complete than a section 8 notice. (See section 5.1.4 of text.)

A.21 COMBINED SECTION 5 AND SECTION 8 NOTICE (6) VS. MINIMUM GUIDANCE OPTION (7)

Coverage:	Coverage under both options is the same when section 5 notices are submitted under option 6. However, when section 8 notices are submitted, coverage differs because "small processors" are exempt from reporting.
Reporting Requirements:	Same as differences described in A.20.
Regulatory Authority:	Same as differences described in A.20.

CHAPTER 9

POSSESSION OR CONTROL

Under section 5 of the Toxic Substances Control Act (TSCA), when firms submit a premanufacture notice to the Environmental Protection Agency (EPA), they must include with it any test data[53] in their possession or control which is related to the health or environmental effect of any manufacture, processing, distribution in commerce, use, or disposal of the substance in question.[54]

In order to determine the scope of information that firms are responsible for submitting, EPA has proposed three alternative definitions for "possession or control." In this paper, the costs to industry of these alternatives will be assessed. The assessments will be based on information in the public record, on literature about the state of the art of chemical information science,[55] and on telephone interviews with chemical information scientists and experts in transnational data flow problems.

In the following sections we will:

- specify the options under consideration;
- specify the type of costs and magnitude of costs incurred by industry under each option; and
- estimate the relative burden of each option to industry.

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[53] Test data is defined as "data including chemical identity from a formal or informal study, test, experiment, recorded observation, monitoring or measurement; and information concerning the objectives, experimental methods and materials, protocols, results, data, analyses (including risk assessments), and conclusions from a study, test, experiment, recorded observation, monitoring or measurement." Federal Register, Vol. 44, No. 7, January 10, 1979.

[54] TSCA, section (5)(d)(1)(B).

[55] Chemical information science is the study of how to classify and organize chemical information.

POSSESSION OR CONTROL OPTIONS

EPA has provided three alternative definitions for "possession and control." All of them define the sources of data as:

- company files;
- commercially available data bases to which the company has purchased access (called commercial data bases); and
- files maintained in the course of employment by employees or agents associated with the commercial development of the new chemical substance (called employee files).

The definitions also include the concept of a parent company. A parent company is considered to have control over another company if it owns or controls 50 percent or more of the other company's stock.[56]

The options differ on two issues. The first is whether submitters who are not parent companies have control of the files of their parent companies and the files of other subsidiaries of their parent companies. We call this the "one-way vs. two-way" issue. If a company is considered to have no control over the files of its parent or of its parent's subsidiaries, then "possession and control" only creates a reporting responsibility in one direction: the parent is responsible for its subsidiaries' files. If a company is considered to have control over these files, then "possession or control" creates a reporting responsibility in two directions: the parent and subsidiaries are defined to have access to each other's files. Option 1 and option 3 are two-way options and option 2 is a one-way option.

The other issue is whether companies are defined to have control over files of associated companies whether or not they were involved in the commercial development of the chemical. This is called the present venture issue. Many companies in the chemical industry have numerous subsidiaries and/or sister subsidiaries. Rarely, if ever, will all of them participate in the development of a chemical. The issue becomes, should all companies be required to search through their files whether or not they participated in the present venture? Option 1 and option 2 are present venture options and option 3 is not.

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[56] For financial purposes, APB Opinion #18 (March 1971) defined control as the ability of the investing company to determine the operating and financing policies of another company in which they own shares of the voting stock. Control is assumed when the investing company owns over 50 percent of the stock. The Export Administration Regulations dealing with restrictive trade practices or boycotts (43 FR 3508) use a much broader definition, but they use "control in fact" rather than just "control".

Option 1: The Two-Way Present Venture Option

Test data in the "possession or control" of the submitter would include test data in the possession or control of any of the following as long as they were associated with the submitter in the research and development, test marketing, or commercialization of the substance:

- the submitter's subsidiary;
- the submitter's parent company; and
- a subsidiary of the submitter's parent company.

Included among sources of data are commercial data bases, company files, and employee files for each of the above parties.

This is the option proposed by EPA in the January 10 proposal. It is a two-way option in that reporting requirements are the same whether or not a parent or its subsidiary submits a notice, since both are defined to have access to each other's files. It is a present venture option in that "possession or control" is limited to companies involved in the present venture of commercializing the chemical in question.

Option 2: The One-Way Present Venture Option

Under this option, information in the "possession or control" of the submitter would only include information in the possession or control of the submitter and its subsidiaries. The submitter would be presumed not to have access to its parent's files or its parent's other subsidiaries' files. As in option 1, the definition is limited to those companies associated with the submitter in the research and development, test marketing, or commercialization of the substance. As in option 1, the sources of information may be commercial data bases, company files, and employee files.

Option 3: The Two-Way Non-Present Venture Option

As in option 1, test data in the "possession or control" of the submitter would include test data in the possession or control of the submitter's subsidiaries, its parent, and any other subsidiaries of its parent. Unlike option 1, the definition is not limited to the present venture. All these companies must check through their files to see if they have ever done any work related to the chemical in question whether they are involved in the current venture or not. As in options 1 and 2, sources of data include commercial data bases, company files, and employee files.

Under all three options, EPA may elect to provide some mechanism to allow the submitter to demonstrate good faith in attempting to obtain the information required from companies over which the submitter has no real control. This especially applies to foreign subsidiaries and parents. We will look at the economic impact of each option with and without this mechanism.

EXHIBIT 9-1

DIFFERENCES BETWEEN OPTIONS

	One-Way	Two-Way
Present Venture	Option 2	Option 1
Non-Present Venture		Option 3

INDUSTRY COSTS

This section discusses the types of costs faced by industry. It includes a discussion of the factors affecting the magnitude of cost and then analyzes the five kinds of costs:

(1) costs of gathering data from company files;

(2) costs of gathering data from commercial data;

(3) costs of gathering data from employee files;

(4) costs associated with international data flow; and

(5) intangible costs.

The first four kinds of costs are all direct out-of-pocket costs. Intangible costs encompass costs resulting from delays in the introduction of new chemicals, trade secret disclosure, and uncertainty. All costs are pre-submission costs, but they each have their counterpart post-submission cost. For example, EPA may require supplemental data the scope of which is determined by "possession or control". Potential confidentiality costs are mostly post-submission costs but some are pre-submission costs.

Factors Affecting the Magnitude of Costs

For any given company, there are three factors that can affect the magnitude of costs. These are:

- the size of the company;
- the sophistication of its chemical information system; and
- the definition of possession or control that EPA chooses.

The size of the company affects the quantity of information that must be gathered. A large company requires more time to gather information than a small company with the same information system. This occurs because large companies have more employees and more projects, and they may perform more thorough tests on new chemicals than small companies.

The sophistication of a company's chemical information system can dramatically affect the costs of gathering information in its "possession or control". With a modern, computer-based information system, a large multinational chemical company can gather all of the information in this possession or control in less than a day. At the other extreme, a company with a crude manual system may require many days to gather the same information.

A company with a modern system is able to store a large number of document titles and classify them by chemical characteristics, uses, or any other category. This allows the company to find the documents pertaining to a particular subject quickly. For a survey of the state of the art of chemical information science, see the appendix to this chapter.

It should be expected that large companies will have better information systems than small companies. They have more capital to invest in a large information system, and they are able to hire the technical people necessary to install and maintain such a system. Furthermore, because of the size of their data bases, they have more incentive to install a sophisticated system.

Since the level of sophistication of a company's information system will affect the costs of gathering information in "possession or control," companies will have an incentive to improve their information systems. This does not mean that without TSCA no company would have improved its information system. According to chemical information science experts, companies were radically improving their information systems long before TSCA; improvement was necessary to keep up with the growth of information. But TSCA increased the incentive to improve information systems. Therefore, when analyzing the costs of "possession or control," we must consider the state of the industry after being affected by these costs. We must also consider the costs of providing for these changes.

For the purposes of this analysis, we will consider three classes of companies in the chemical industry. Class 1 companies will include those companies with crude information systems that decide not to improve them despite the demands of TSCA. The only costs they bear will be those connected with individual notices. As time goes on, these companies will improve their systems, but not because of TSCA. Class 2 companies will include those companies that decide to improve their information systems. They will incur lower notice costs, but they will also spend money to install and maintain their new systems. It should be noted that only those costs that will not be incurred without TSCA will be considered a cost of TSCA. Since most companies will eventually improve their information system with or without TSCA, only part of the installation and maintenance costs will be attributed to TSCA. For example, if a company decides to install a computer five years earlier than it might have because of TSCA, then the costs attributed to TSCA should be the cost of installing the system minus the cost of installing it five years later (properly discounted), plus the cost of maintaining the system for five years. If the company installs a system solely meant to deal with TSCA, then it should be totally costed to TSCA. An example of this might be a special program used to gather and organize TSCA-related material. Class 3 companies will include those companies that already have modern systems and would have continued updating them without TSCA. Like Class 1 companies, they will only incur costs connected with each notice. No installation or maintenance costs should be attributed to TSCA because TSCA is not the motivating force in installing the system. But, such costs will be much lower than those of class 1 companies.

All companies are to some extent level 2 companies and will have to adjust their information systems to some degree to deal with TSCA. They will differ in the degree of system improvement they make.

The last factor affecting costs is the definition of "possession or control" that EPA chooses. Because the only difference between the options is the number of corporate entities that must supply information, we can consider the cost of gathering data for each corporate entity and add them together. To this sum, we should add the cost of transmitting data between entities to derive the total cost of each option. For example, if a company has five subsidiaries, the cost of gathering information for each subsidiary and the parent can be determined separately, then added together. The cost of sending the data to the parent is then added, to get the total cost of gathering data.

Thus, the approach here is to determine the costs of gathering data for each "level" company. The cost of each option will become a function of this cost and of the number of corporate entities subject to data-gathering requirements.

Because small firms with no subsdiaries or parents are not be affected by the definition of possession or control, they will not be considered here.

Cost of Gathering Data from Company Files

The first cost of gathering data is the cost of gathering data from the company files maintained by the section 5 notice submitter. All companies, whatever the sophistication of their information retrieval system, incur some variable costs connected with each submission. "Level 2" companies also incur some fixed costs connected with installing and maintaining a new information system.

Class 1--Crude Information Systems. All companies are assumed to have at least an indexed manual filing system for their documents. Without an indexed filing system, an employee would have to search through half the existing documents, on average, each time he needed one. If documents are only stored by subject, time requirements are significantly lower than they would be without any indexed system.

For firms with manual systems, costs of gathering data can be broken into the cost of searching for documents and the cost of gathering and preparing documents. If the index does not list documents, then a worker with a technical background would have to search for and gather the necessary documents, and a clerk would prepare them. If a document index does exist, then a technical worker may have to search through the index, but a clerical worker could do the rest.

Companies may also have computerized information systems that are not well suited for TSCA. In the worst case, the cost of searching for and gathering data would be the same as that for manual systems. However, it would probably be much less because the time required to search through an index would be significantly less. The cost of running the computer for the time needed to do a search would also be included, but this would be very low.

It should be remembered that, even without TSCA, most companies are improving their information systems. Whatever the cost of gathering information in company files, it will decrease with time.

Class 3--Sophisticated Information Systems. Companies with sophisticated information systems will bear the same type of costs as Class 1 companies, but the costs will be lower. Some companies now have systems that allow a technical worker to search through a company's document titles by computer in fifteen minutes; and they have clerical workers who can gather the documents in less than a day. Thus, the cost becomes insignificant.

As computers become able to store data more efficiently, firms may become able to store the actual documents, as well as the titles, on computer. This would reduce the costs of gathering data from company files even further.

Class 2--Improved Information Systems. Class 2 companies are those that install sophisticated systems in order to deal effectively with the reporting requirements of TSCA. The cost of gathering data for a notice will be the same as that for a Class 3 company. But there will also be some fixed costs connected with installing and maintaining the new system. They are fixed in that they do not depend upon the number of notices submitted.

The total value of these fixed costs is equal to the discounted value of each year's expenditure on fixed installation and maintenance, minus each year's non-TSCA benefits derived from the new system. It must be remembered that eventually the company would have installed a new system (not necessarily the same one) anyway. Therefore the expenditures for installing and maintaining the system later must be deducted from costs, while the savings derived from the later system must be deducted from benefits. This means that the only significant costs and benefits are those accrued between the time the TSCA-motivated system was installed and the time another similar system would have been installed in the absence of TSCA.

The costs associated with installation include costs of buying hardware and/or software, installation costs, programming costs, and testing costs. The cost of the system that would have been used in the absence of TSCA should be subtracted from this after being properly discounted.

The costs of maintaining the new system are only equal to the marginal costs. If no new employees are needed to maintain the system, then there are no costs. For those companies that had no computer system, maintenance costs will be sizable. For those that had computer systems and only had to add additional programs, the maintenance costs should only be equal to the costs of maintaining the new programs and data files.

The net present value of the fixed cost of systems that are installed because of TSCA is not currently known, but it is negative. If it were positive, companies would have developed the systems without TSCA. It also seems that in most cases the negative number will be a relatively small one because in a few years the company probably would have instituted the changes without TSCA. This would seem to indicate that the improved system has a positive rate of return, but that other projects have higher rates of return. The rate of return rises as the information demands of the company increase and as other companies solve some of the "start-up" problems.

Cost of Gathering Data from Commercial Data Bases

The second source of information that the submitter must search is the commercial data bases to which it has purchased access. The fact that the submitter has access to the files implies it has access to the programs necessary to use the data bases efficiently; the two are sold together. The cost of searching through those files depends upon the size of the data banks, the efficiency of the commercial programs used to access them, and the cost of computer time. Carol Haberman from the Toxicology Data Bank estimates that, at most, 15 minutes would be required to get information from all data bases on a specific chemical.[57/] During peak hours, computer time costs $15.00 per hour.[58/] It costs 12 cents to print a page of output. Toxicology Data Bank provides access to a number of different chemical data banks (a reasonable upper limit on the number of data banks to which any one firm would have access). The cost of gathering data is equal to the computer costs plus the labor costs and should be minimal, considering the time involved. If the company had already generated a list from the commercial data bank in the course of researching the chemical, then it does not have to generate the list again and the cost is zero.

What will happen to these costs over time is not certain. Whether computer costs will increase or decrease is not clear, nor is it clear how user firms will react to the increase in the number of available data banks.

[57/] Telephone conversation with Carol Haberman, Technical Information Specialist, Toxicology Data Bank, April 30, 1980.

[58/] The cost of computer time is expected to increase soon.

Cost of Gathering Information from Employee Files

The last source of data is files maintained by employees in the normal course of employment. One method of collecting data would be for the company to publish in prominent places of a newsletter or post a request for pertinent information. The costs associated with this method would be the cost of preparing a news item and posting it if necessary, the cost of each employee searching through his files, and the cost of preparing documents for the public record. These costs will depend upon the number of technical workers and the condition of their files.

Because the definition of files maintained by employees is broad in the proposed regulation--it includes such information as conversations between employees--the employee files would be the most expensive source to search. It also involves the greatest chance of neglect in collecting relevant data, and it will be the most difficult part of the requirement for EPA to enforce.

Cost Associated with International Data Flow

The notice information requirements may cause significant problems for those companies with foreign subsidiaries or parents. In the last few years, a number of laws have been passed to restrict the flow of information across national borders. Most of these have been written as privacy laws, but they have been used to restrict the flow of information harmful to a nation's security. Fourteen industrial nations, including all of our major trading partners have such laws.59/ Thus, test data could be restricted for national security reasons.

The scope of these laws is unclear. Some experts feel there are no laws that directly restrict the flow of scientific information.60/ Chris Vizas of the House Subcommittee on Government Information and Individual Rights cites a statute recently passed in Great Britain, the Protection of Trading Interest Act of 1980, specifically dealing with commercial information which includes scientific information.61/ Vizas also points out that the International Traffic in Arms Regulations of this country have been used in the past to restrict the flow of scientific information out of the country. The ban on technology for the Soviet Union is a case in point.

59/Telephone conversation with Alden Heintz, Vice President, Industrial Corporate Operations, Tymshare Corporation, May 2, 1980.

60/Telephone conversations with Alden Heintz, Tymshare Corporation, May 2, 1980; Geza Feketekuty, U.S. Trade Representative's Office, Assistant U.S. Trade Representative for Policy Development, May 1, 1980; Tim Donovan, Executive Director, Transnational Data Reporting Service, May 8, 1980.

61/Telephone conversation with Chris Vizas, May 2, 1980 and May 6, 1980.

All the experts we consulted agree that a great potential exists for restrictions of scientific data flow. Vizas mentions stronger enforcement of existing laws, and all the experts note the potential for new stronger laws. One expert feels that restrictions will become worse before they get better. He says no one has thought through the real costs of restricting information in order to protect domestic industry and preserve secrets, and few have looked at the increased costs of doing business created by this practice.

The costs of transmitting foreign data are also being kept artificially high by restrictions on the telecommunications and computer industries in many countries. Japan, France, Germany, and Brazil (as well as others) all restrict the use of foreign telecommunications and computer systems.62/

Gathering information from foreign companies could involve significant costs, depending on how foreign nations decide to handle the whole issue of transnational data flow. The costs will depend greatly upon what standards EPA sets.

Intangible Costs

Three intangible costs are connected with submitting information for section 5 notices. The first is the cost of a time delay caused by the information gathering process. This should be negliglible, except when foreign regulatory agencies are involved. Foreign governments may restrict the flow of information for months. The "good faith" standard that EPA establishes will determine the cost of this time delay.63/

The second cost is the cost of the uncertainty of whether EPA will consider the company's effort a good faith effort. This cost will be determined by the policies of EPA. As time passes and companies determine what constitutes a good faith effort, these costs should decrease.

The final cost is the cost of disclosing confidential data. Many industry members feel this will be the most significant cost. The cost of trade secret disclosure may increase when data requested by EPA is in a foreign country. The foreign government may require the company to submit the information to its agencies for review to determine that disclosure will not be in violation of its laws. Thus, the chemical company will provide the data to two governments instead of one, increasing the possibility of disclosure.

62/Telephone conversation with Alden Heintz, Tymshare, May 2, 1980.

63/This should be considered in some of the issues, there is a cost in a time delay caused by EPA extending the review period under section 5(c). But since the definition of "possession or control" will not affect the magnitude of this cost, it need not be considered in this issue.

Summary of Costs

With the exception of the costs of transnational data flow, all the above costs are incurred by single corporate entities. To determine the cost of each option, we need only decide how many corporate entities are covered by the option. The cost of transnational data flow is the cost of sending data from foreign companies to an associated domestic submitter. The cost of sending data from one domestic company to another will not exceed postage costs which are negligible.

Costs of collecting data for a corporate entity can be divided into tangible (direct out-of-pocket) and intangible costs. The tangible costs are modest with the possible exception of gathering data from employee files. The intangible costs may be very high. They will depend on the policies of EPA and of foreign regulatory agencies.

COST OF OPTIONS

Option 1: The Two-Way Present Venture Option

Under option 1, the submitter must provide information from the files of any of the following companies if they were associated with the submitter in the research and development, test marketing, or commercialization of the substance for which a notice is being submitted:

- the submitting company;
- its subsidiaries;
- its parent company; and
- any subsidiaries of its parent company.

The cost of option 1 is the cost of gathering data from each company's corporate files, each company's commercial data files, and each company's employee files. The cost does not depend on who submits the notice.

The cost of gathering data from each company's corporate files will depend upon the level of sophistication of each company's information system, each company's role in the development of the chemical, and the degree of integration in the information systems between corporate entities. Without integration between systems, the total cost is equal to the cost of gathering data from corporate files plus the cost of sending the data to the submitter. (The cost of gathering data has been discussed in detail.) The cost of sending it may include telecommunications costs, mail costs, and the cost of time delays. If any corporate entities sending data are in foreign nations, it may also include the cost of filing for permission to send data across national borders. This includes the actual cost of filing, the cost of lost confidentiality (in many cases, to send data across national borders, the contents of those data must be revealed), and the cost of uncertainty. If a foreign government does not allow information to be sent, then the cost may range from the cost of filing for permission to send the data to the cost of having a notice rejected, depending on how EPA defines good faith efforts in such situations. If the companies' information systems are totally integrated, costs may be dramatically reduced. Some multinationals store copies of all research data in a central library. With a modern information system, the cost of gathering data for all corporate entities approaches the cost of collecting it for only one entity.

If companies are working together on a project, it is reasonable to expect communication between them and individual company familiarity with the other companies' progress. If all companies involved in a venture are given copies of all relevant work, then for notice purposes, there is total integration.

The cost of gathering data from commercial data files is similar to the cost of gathering data from each corporate entity's commercial data files plus the cost of sending the data to the submitter. If two entities have access to the same commercial data file, then only the one with the lower transmittal costs needs to gather and send the data. If all entities have access to the same data files, then the cost for all entities is reduced to the cost for one entity.

If all entities are domestic, then total cost should be minimal. If some entities are foreign, then they may have access to other commercial data bases. This could increase costs in the short-run because of transnational data flow problems. Again, the "good faith" standard which EPA establishes becomes important, but there has been a trend towards the development of international data bases. Germany and some other EEC countries are in the process of joining the major American data bank, the Chemical Abstracts Service. As this trend continues, all companies will gain access to the same data banks and will reduce costs associated with transnational data flow in the long-run.

The cost of gathering information from employee files will again be equal to the sum of gathering information for each entity plus the cost of transmitting the data. Little can be done to integrate employee files. Transmittal costs will still be minimal for domestic entities but may become very high for foreign entities. Most restrictive foreign laws are directly aimed at "personal data". Because information from employee files is somewhat personal, it may be difficult to transfer.

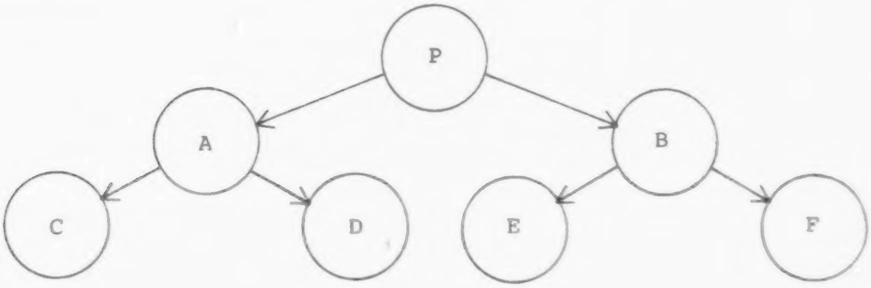
Each piece of information that is submitted has a potential cost of lost confidentiality. The larger the number of companies that must submit data, the higher the total costs of lost confidentiality. Furthermore, if foreign, associated companies are required to expose their data to foreign regulatory agencies before they can send it to their domestic submitter, the cost of lost confidentiality would be high no matter what rules EPA establishes for confidentiality.

The only estimate left to be made is the number of companies involved in the development of a new chemical. In many cases, only one entity is involved in the process. In other situations, a few entities will be involved. For example, Eastman Chemical does a great deal of joint research with Eastman Kodak research labs, and ICI Americas receives technical help from its British parent. The final possible joint research relationship involves companies such as Exxon Chemical and Chevron Chemical. Most research done for these companies is done by another subsidiary of their parents. In most cases, the total number of companies exposed to reporting requirements should be limited and should only include companies with a reasonable probability of providing relevant data.

Option 2: The One-Way Present Venture Option

In option 2, the submitter must only provide information in its possession or control or in its subsidiaries' possession or control. As in option 1, only those companies involved in the present venture must provide information. The cost of gathering information now depends upon who the submitter is. This section will refer to companies by the letters in Exhibit 9-2.

EXHIBIT 9-2



Total costs may again be broken down into costs of gathering data in company files, in commercial data files, and in employee files. As in option 1, the total cost is equal to the sum of the individual costs of gathering data and of sending it to the submitter for each entity. The significant difference between options 1 and 2 is the number of entities that are subject to reporting requirements.

If company P is the submitter, then the cost is the same for option 1 and option 2. But if company A is the submitter, only companies A, C, and D must provide information. The reduction in cost is the cost of gathering and transferring data from companies P, B, E, and F. Costs may be further reduced if company P takes control of all commercial data banks. Company P can let its subsidiaries use the data banks, but it does not have to search through the banks.

The submitter of a notice is the manufacturer of the new chemical. Many chemical companies are organized by product lines, each product line being manufactured by a different subsidiary or division. If companies have divisions rather than subsidiaries, then option 1 and option 2 have the same costs. But if companies have subsidiaries, then option 2 could be much less costly. There may be some incentive for companies to change their divisions into wholly owned subsidiaries if this option is adopted.

Option 3: The Two-Way Non-Present Venture Option

According to option 3, the submitter is presumed to be in possession or control of its own files, its subsidiaries' files, its parent's files, and its parent's other subsidiaries' files, even if some of them had nothing to do with the development of the new chemical. Again total costs are equal to the sum of costs of gathering data and transmitting it for each entity. But the number of entities subject to reporting requirements significantly increases. Using option 1 the number of entities that must report data appears to be between 1 and 4. Exhibit 9-3 gives the number of entities that must report for a number of companies under option 3.

EXHIBIT 9-3

NUMBER OF ASSOCIATED COMPANIES UNDER OPTION 3

Company	All Companies	Number of Entities That Must Report Chemical Companies
Amax	42	2
Akzona	17	12
Amoco Chemical	55	1
Ashland Chemical	25	0
BASF Wyandotte	21	21
Celanese Corporation	22	22
DuPont	41	41
Engelhard Mineral & Chemical	32	4

Note: These are conservative estimates taken from Standard & Poors and the National Register Publishing Company's Corporate Affiliations.

Summary

Possession or control is an indicator of the depth to which submitters must reach in filing a section 5 notice. The more deeply the submitter must reach, the greater are the pre-submission costs in both time and money. Thus, pre-submission possession or control costs increase as the procedure progresses from a one-way present venture option to a two-way non-present venture option.

The rationale for post-submission possession or control costs parallels the logic presented previously. Potential post-submission, out-of-pocket costs decrease with the increasing depth of possession or control because the more information is required at time of submission, the less post-submission information will be required.

Potential, post-submission delay decreases as the depth of possession or control increases because delaying actions are less likely to be invoked when there is additional information provided initially.

The potential for trade secret disclosure increases with the scope of possession or control. The relationship between potential restrictive actions and possession or control is similar. The more deeply submitters are required to reach, the more likely it is that some submitters will choose not to enter the market because the perceived notice requirements are too great.

EXHIBIT 9-4

COMPARISON OF COSTS ATTRIBUTABLE TO POSSESSION OR CONTROL

	OPTION 1 Two-Way Present Venture	OPTION 2 One-Way Present Venture	OPTION 3 Two-Way Non- Present Venture
Pre Submission Costs			
Out-of-Pocket			
Company files	2	1	3
Commercial data files	2	1	3
Employee files	2	1	3
Transnational data flow	2	1	3
Intangible Costs			
Delay	2	1	3
Potential trade secret disclosure	2	1	3
Uncertainty	2	1	3
Post Submission Costs			
Potential out-of-pocket	2	3	1
Potential delay	2	3	1
Potential trade secret disclosure	2	1	3
Uncertainty	2	3	1
Potential restrictions	2	1	3

A "1" indicates the least costly alternative.

APPENDIX TO CHAPTER 9:

STATE OF THE ART--CHEMICAL INFORMATION SCIENCE

During the last four decades, much work has been done in the chemical industry on chemical information systems. Some of the major milestones include the introduction of a number of notation systems, most notably the Wiswesser System, and the implementation of a number of indexing systems, most notably key word (KWIC and KWOC) indices. Computers have become a necessary tool in the storage, indexing, and retrieval of all information. Today, companies can store internal report citations and index them by key word, chemical characteristics, or uses. With the possible exception of access to the files maintained by employees, all of the demands of the PMN information requirements can easily be satisfied using modern technology.

Most large chemical companies have already developed sophisticated information systems. For example, one company has centralized all documents at its corporate headquarters. It has more than 50 subsidiaries, most of which are in foreign countries. But because the files are centralized, it would take a maximum of one day, largely spent pulling listed documents, to gather information for a PMN.

Another company, a subsidiary of a major foreign chemical company, has tried to integrate the present TSCA regulations into its information systems and has anticipated what EPA (as well as other government agencies such as OSHA) will require. This company set up an internal computer system to deal with the TSCA Inventory requirements. It identified the relevant chemicals and kept records on the reporting status of each one. Presently, physical properties are not stored on the system but will be added in the future. The company has easy access to the information of its parent that is relevant to its own areas of business. It could easily comply with option 1 and 2.

Although there are many large firms not as well equipped as the two profiled above, they all should have sophisticated information systems. Most of their information systems are constantly being updated and adapted to TSCA regulations.

Many companies have written articles about their information systems. These include:

(1) Benson, Frederic R. (ICI Americas), "Research Information at ICI United States, "Journal of Chemical Documentation, 1974.

(2) Skolnik, Herman (Hercules, Inc.), "The Hercules Technical Information Division: Services Special Systems, and R&D," Journal of Chemical Documentation, 1974.

(3) Schultz, John L. (E.I. du Pont de Nemours & Co., Inc.), "Handling Chemical Information in the DuPont Central Report Index," *Journal of Chemical Documentation*, 1974.

(4) Sleng, A., *et al.* (Hoffman-LaRoche, Inc.), "Hoffman-LaRoche's On-Line/Batch Interactive Chemical Information System," *Journal of Chemical Documentation*, 1974.

(5) Gordon, Irving, *et al.* (Hooker Chemical Corp.), "Design and Implementation of a Chemical Information Center," *ASIS Journal*, 1972.

(6) Edge, Eleanor B., *et al.*, (E.I. du Pont de Nemours & Co., Inc.), "System for Indexing Research Reports Using a Punched Card Machine," *American Documentation*, 1957.

(7) Costello, J. C., Jr. (E.I. du Pont de Nemours & Co., Inc.), "Storage and Retrieval of Chemical Research and Patent Information by Linds and Roles in DuPont," *American Documentation*, 1961.

(8) Mendenhall, Donna M. (Uniroyal Chemical), "Cost Comparison of Four Data Input Methods," *Journal of Chemical Documentation*, 1974.

(9) Brown, Horace D., *et al.* (Merck & Co., Inc.), "The Computer-Based Chemical Structure Information System of Merck Sharp and Dohme Research Laboratories," *Journal of Chemical Information and Computer Sciences*, 1976.

(10) Merritt, R. L., (Shell), "The Shell Chemical File System," *Journal of Chemical Documentation*, 1974.

Most of these articles were written before 1976, and none mention TSCA--a fact which indicates that chemical information science would progress with or without TSCA. Firms must worry about information requirements of other government agencies (OSHA, FDA, other offices of EPA). Most importantly, they must satisfy their own internal information requirements. One expert thought that the pharmaceutical and pesticide firms had the best information systems. The stringent regulations concerning these industries have probably motivated the industry to improve their information systems, but only indirectly. There are no general clauses in FIFRA or the 1962 FDA amendments requiring firms to submit ". . . any test data in their possession or control. . . ."[64] Instead, the laws are set up to require specific tests. Firms have set up good information systems to aid them in doing research, not to pull reports indiscriminately from their files.

As time goes on and chemical information systems become more sophisticated, the costs associated with any of the "possession or control" options will decrease. The volume of information will significantly increase, but information science should be able to provide systems capable of dealing with this constant growth.

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[66] TSCA Sec. (5)(d)(1)(A).